REGULATION (EU) 2016 /425
ANNEX III – TECHNICAL DOCUMENTATION FOR PPE

TECHNICAL FILE

REFERENCE NUMBER:

IN ACCORDANCE WITH ANNEX III OF PPE REGULATION (EU) 2016/425

COVERING COVID-19 RELATED EN 166 VISORS

CONTENTS

(*This skeleton Technical File has been produced by SATRA for an authorised representative or manufacturer of Personal Protective Equipment (PPE) to either enter the missing information or use it as an example for guidance. Whichever option you choose, it is important to ensure that all the necessary information is given in a clear, concise and unambiguous format).*

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ANNEX III – TECHNICAL DOCUMENTATION FOR PPE

SECTION 1 – COMPANY INFORMATION.

COMPANY STRUCTURE:

Please include details of the company making the application include structure and background

Ramfoam Ltd, Hainge Road, Tividale, West Midlands, B69 2NR

Parent Company: PJ&PW Holdings Ltd

Ramfoam Ltd was first incorporated in 1995.

Company Number: 03024533.

STATEMENT OF END USE OF PPE:

Disposable or limited use COVID-19 related EN 166 visors to be supplied to non-NHS key workers in, public and private healthcare systems via distributors, retainers or supplied directly to the end users.

HARMONISED STANDARD(S) / SPECIFICATIONS TO BE APPLIED.

EN166:2001 clause 6 - Design
EN166:2001 clause 7.1.1 - Field of vision
EN166:2001 clause 7.1.2.1 - Refractive powers
EN166:2001 clause 7.1.2.2 - Transmittance
EN166:2001 clause 7.1.2.3 - Diffusion of light
EN166:2001 clause 7.1.3 - Quality of materials
EN166:2001 clause 7.1.5.1 - Stability at elevated temperature
EN166:2001 clause 7.1.7 - Resistance to ignition
EN166:2001 clause 7.2.4 - Droplets and splashes of liquids

DECLARATION OF INNOCUOUSNESS

Other than those specified on the user instructions, the products covered by this technical file are not known to contain any materials or substances (including decomposition products) likely to harm the health or hygiene of the user or other person likely to come into contact with the product.

Signed:

Position: Timothy Mulqueen

Date: 16/07/2020

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ANNEX III – TECHNICAL DOCUMENTATION FOR PPE

SECTION 2 – PRODUCTION DETAILS

*(List the production sites for the **final assembly** of all finished items of PPE covered by the Technical File as listed in Section 3 – typically most products will only be produced at a single site but if additional production sites are being used these should be listed).*

PRODUCTION SITE 1

Address: Ramfoam Ltd Hainge Road, Tividale, West Midlands, B69 2NR UK

Products: EN166 Protective visor

PRODUCTION SITE 2

Address:

Products:

PRODUCTION SITE 3

Address:

Products:

SECTION 3 – RISK ASSESSMENT

What are the hazards?	What type of injury may occur?	Rate severity of hazard / injury?	What is the likelihood of the hazard or injury occurring?	Severity x likelihood rating	What design considerations are applied to mitigate the risk of injury	Which standard is being applied to assess the level of protection afforded?
						Complies with clauses: 6 Design, 7.1.1 Field of vision, 7.1.2.1 Refractive powers, 7.1.2.2 Transmittance, 7.1.2.3 Diffusion of light, 7.1.3 Quality of materials, 7.1.5.1 Stability at elevated temperature, 7.1.7 Resistance to ignition & 7.2.4 Droplets and splashes of liquids of EN 166:2001
Airborne liquid droplets of substances and mixtures of harmful biological agents	Contact of all or part of the body with substances, mixtures or biological agents which are hazardous to health that could cause illness	5	4	20	Use of liquid proof transparent materials	

SECTION 4 – GROUP AND PRODUCT DESCRIPTIONS

Group Number / Product code	***Ramfoam Care+***
Product Standard	*EN 166: 2001*
Product code / name	**Product Description**
	Disposable or limited use COVID-19 related EN 166 visors Please include a description of the product including *photographs / annotated assembly drawings showing all the main features of the product. PHOTOGRAPHS TO INCLUDE INSIDE, FRONT AND BACK AND WHERE RELEVANT SIDE ELEVATION OF PRODUCT. Please also include a brief written description to include information such as size range where relevant]*
RAMFOAM CARE+	2-piece design (plus label).
	Headpiece manufactured from Azote® Plastazote® LD33 foam **Specification Sheet – Appendix 01**
	Screen manufactured from Melinex® FS1 or Mitsubishi film **Specification Sheets – Appendix 02**
	Specification Drawings – Appendix 03
	Due to the products unique design, the headpiece is self-adjusting for a comfort fit.
	Complete Product Specification Sheet – Appendix 04

PRODUCT DESCRIPTION CONTINUED.

SECTION 5 – MASTER MATERIAL LIST

(Include all materials used in the product which is being assessed by Annex II of Regulation (EU) 2016/425).

Material/ component	Supplier reference	Name of material supplier	Supplier Address including country	Test report (*report numbers as in Section 8)*
Visor	**Melinex®** FS1	**DuPont Films**	The Wilton Centre Redcar TS10 4RF	**SPC0297461/2018**
Visor	**Hostaphan FACE FS1**	**Mitsubishi Polyester Film**	Kasteler Str. 45 65203 Wiesbaden/Deutschland	**SPC0297461/2018/2**
Headpiece	**Plastazote LD33**	**Zotefoams PLC**	675 Mitcham Road Croydon CR9 3AL UK	**SPC0297461/2018 & SPC0297461/2018/2**
Please see appendix 3 for material dimensions.				

SECTION 6 – COMPLIANCE WITH PPE REGULATION (EU) 2016/425 ANNEX II EHSR

The products covered by this technical file address the below clauses in Annex II of Regulation (EU) 2016/425 by complying with the following clauses of EN 166:2001

EN166:2001: 6 Design, 7.1.1 Field of vision, 7.1.2.1 Refractive powers, 7.1.2.2 Transmittance, 7.1.2.3 Diffusion of light, 7.1.3 Quality of materials, 7.1.5.1 Stability at elevated temperature, 7.1.7 Resistance to ignition & 7.2.4 Droplets and splashes of liquids

GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against the risks against which it is intended to protect.

1.1. Design principles

1.1.1. Ergonomics PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

1.1.2. Levels and classes of protection

1.1.2.1. Optimum level of protection The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2. Innocuousness of PPE

1.2.1. Absence of inherent risks and other nuisance factors PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and strength PPE must be as light as possible without prejudicing its strength and effectiveness. PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.4. Manufacturer's instructions and information In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on: (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions; (b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE; (c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts; (d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use; (e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components; (f) where applicable, the type of packaging

suitable for transport; (g) the significance of any markings (see point 2.12); (h) the risk against which the PPE is designed to protect; (i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation; (j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE; (k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used; (l) the internet address where the EU declaration of conformity can be accessed. The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.1. PPE incorporating adjustment systems If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.3. PPE for the face, eyes and respiratory system Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised. The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user. If necessary, such PPE must be treated or provided with means to prevent misting-up. Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.9. PPE incorporating components which can be adjusted or removed by the user Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market. Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

2.14. Multi-risk PPE PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.2. Protection against cutaneous and ocular contact PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended. To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear. Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the

names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

SECTION 7 –USER INFORMATION AND PRODUCT MARKING

(Customise this text to meet your requirements by adding missing details. Remember – always ensure that the instructions are clear and free from ambiguity.

CAREFULLY READ THESE USER INSTRUCTIONS BEFORE USING THIS VISOR

Applicable to products: *(Ramfoam Care+).*

Manufacturer: *(Ramfoam Ltd, Hainge Road, Tividale, West Midlands B69 2NR).*

Notified body: Module B and C2 - SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, D15YN2P. Republic of Ireland (Notified Body 2777). Declaration of conformity (www.ramfoamprotect.com/doc)

These products are classed as Category III Personal Protective Equipment (PPE) by the European PPE Regulation (EU) 2016/425 and have been shown to comply with this Regulation through limited testing against the Harmonised European Standard EN 166*:2001 (*see below).

This product is designed to provide some protection against contact with airborne droplets that may constitute a biological hazard. **However, always remember that no item of PPE can provide full protection and care must always be taken while carrying out the risk-related activity. Never use this visor for protection against other hazards for which the product is not design for or tested against**

PERFORMANCE AND LIMITATIONS OF USE – These products have been tested in accordance with EN 166: 2001 Clauses: 6 ¦ Design; 7.1.1 ¦ Field of vision; 7.1.2.1 ¦ Refractive powers; 7.1.2.2 ¦ Transmittance; 7.1.2.3 ¦ Diffusion of light; 7.1.3 ¦ Quality of materials; 7.1.5.1 ¦ Stability at elevated temperature; 7.1.7 ¦ Resistance to ignition;7.2.4 ¦ Droplets and splashes of liquids

FITTING AND SIZING – To put on and take off products, *(Pull rear fin and place over head).* Only wear products of a suitable size that are correctly adjusted. Products which are too loose may not stay in place and if too tight will be uncomfortable. The size of these products is marked on a label attached at and they are available in the following sizes: *(One size, self-adjusting comfort fit – product may need slight stretching)*.

COMPATIBILITY – To optimise protection, it will be necessary to use these products with suitable gloves/gowns/masks. In this case, before carrying out the risk-related activity, consult your supplier or supervisor to ensure that all your protective products are compatible and suitable for your application. Warning - Parts of the visor that come into contact with your skin may lead to allergic reactions. In this case please discontinue use and seek medical advice.

STORAGE AND TRANSPORT – When not in use, store the visor in a well-ventilated area away from extremes of temperature, in a dark area away from sunlight. Never place heavy items on top of it. If possible, avoid excessive folding and preferably store it hanging vertically. If the product is wet, allow it to dry fully before placing it into storage.

OBSOLESCENCE - This visor has a shelf life of 3 years. Service life will depend on usage conditions but the visor should be disposed of and replaced if badly scratched or damaged in some way that prevents safe use

REPAIR – If the visor becomes damaged, it will NOT provide the optimum level of protection, and therefore should be immediately either replaced or repaired. Never use the damaged product. Repair of *(repair of product is not permitted)*.

CLEANING –Only use the following recommended cleaning treatment - Rinse with warm soapy water NEVER use solvent based cleaning agents *(Whilst the headband is reusable and the visor is replaceable – the local policy on reusing and cleaning should be consulted.)*

MARKING – The product is marked with:

i. The CE mark showing that the product meets the requirements of the PPE Regulation (EU) 2016/425.
ii. Identification of the manufacturer and the product code/Article number.
iii. The book pictogram indicating read these instructions

SECTION 8 – QUALITY CONTROL PROCEDURES

[Give a brief summary of the quality procedures used by the manufacturer to ensure ongoing consistency of bulk production. Include details of sampling procedures used and tests carried out. Acceptable relevant documents include quality workflow charts and copies of ISO 9001 certificates.
[Note for Category 2 items of PPE this section will not be assessed by SATRA]

Quality Control Procedures – Appendix 05

SECTION 9 – TEST REPORTS

Product code or material reference	Standard / Clause	Report Number
Ramfoam Care+	BS EN166	**Appendix 06**
LD33 Plastazote®	ISO 109933	**Appendix 07**

SECTION 10 - DESIGN CALCULATIONS, INSPECTIONS AND EXAMINATIONS.

Product code or material reference	Standard / Clause	Reference to design calculation, inspection or examination report
Ramfoam Care+	BS EN166	**Appendix 06**

(Append copies of all relevant documents where design calculations, inspections or examination of products or materials has been carried out as a means of showing compliance with the essential health and safety requirements)

INFORMATIVE ANNEX

The following is an extract from PPE Regulation (EU) 2016/425 Annex III which outlines the criteria of the Technical Documentation:

“The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 of the above Regulation and set out in Annex II.

The technical documentation shall include at least the following elements:

(a) a complete description of the PPE and of its intended use;
(b) an assessment of the risks against which the PPE is intended to protect;
(c) a list of the essential health and safety requirements that are applicable to the PPE;
(d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
(e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
(f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
(g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
(h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
(i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
(j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
(k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
(l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
(m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements. “

AZOTE®

Plastazote® LD33

Low Density Polyethylene Foam

Product Information

Typical Values

Plastazote® is a closed cell, cross-linked polyethylene block foam manufactured using Zotefoams unique production process.

The values provided in this product information represent data gathered from random samples of our production of **Plastazote® LD33** foam and represent typical data. These are given to the best of our knowledge and should be considered as guidance for selecting a suitable grade for a given application.

Property	Test Standard	Units	Typical value
Apparent Density			(nominal)
Skin/Skin	BS EN ISO 7214:2012	kg/m³	33
Cell Size (Cell Diameter)	Internal	mm	0.4
Compression Stress-Strain	BS EN ISO 7214:2012	kPa	
25% compression	25 mm cell-cell		66
50% compression			133
Tensile Strength	BS EN ISO 7214:2012	kPa	419
Tensile Elongation		%	149
Flammability			
Automotive	FMVSS.302 – Burn rate	<100mm/min.	Pass at 9mm
Compression Set	BS EN ISO 7214:2012	% set	
25% comp., 22hr, 23°C	25 mm cell-cell		
½ hr recovery			9
24 hr recovery			4
Tear Strength	BS EN ISO 8067:2008 Method B	N/m	1888
Shore Hardness	BS EN ISO 868:2003		
OO Scale			58
Recommended maximum operating temperature*	Internal	°C	95
Water absorption	ISO 2896:2001 Ed3.	%	<1
Thermal conductivity	ISO 8301:1991	W/mK	0.039
Mean temperature 10°C			

*** RECOMMENDED MAXIMUM OPERATING TEMPERATURE**
The maximum operating temperature shown is defined as the temperature which will typically cause a linear shrinkage of 5% after a 24hr exposure period, using sample dimensions of 100mm x 100mm x 25mm. This figure is provided for general guidance only. The actual level of shrinkage the foam will undergo at any particular temperature is dependant on a number of system variables such as, sample dimensions, cell size, loading conditions and exposure period.

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Any information contained in this document is, to the best of the knowledge and belief of Zotefoams plc and of Zotefoams Inc. (together herein referred to as **ZOTEFOAMS**), accurate. Any liability on the part of **ZOTEFOAMS** or any subsidiary or holding company of **ZOTEFOAMS** for any loss, damage, costs or expenses directly or indirectly arising out of the use of such information or the use, application, adaptation or processing of any goods, materials or products described herein is, save as provided in **ZOTEFOAMS'** conditions of sale ("Conditions of Sale"), hereby excluded to the fullest extent permitted by law.

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Zotefoams plc Management systems are covered by the following:

Quality
FM 01870
ISO 9001:2008

Safety
OHS 52538
OHSAS 18001:2007

Environment
EMS 36270
ISO 14001:2004

APPENDIX 01

HOSTAPHAN®

Preliminary data sheet

Hostaphan® FACE FS1

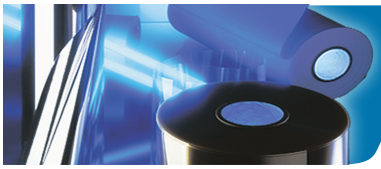
Glass clear polyester film for face shields

Hostaphan® FACE FS1 is a highly transparent PET- film that is chemically primed on one or both sides to provide the slip necessary to handle and wind the film. Hostaphan® FACE FS1 is used in face shield applications and fullfills the optical requirements set forth in the standard for Personal Eye Protection EN 167:2001, § 4.2.2.

The film is **not intended** for use in the manufacture of impact resistant or industrial chemical face shields or goggles, except as an adjunct to the primary barrier, as it does not confer significant impact or corrosion resistance.

Typical properties

Property	*Thickness µm*	*Units*	*Value*		*Test Method*	*Test Conditions*
			MD	*TD*		
MECHANICAL						
Tensile strength	175, 250	N/mm²	190	220	ISO 527-1 and ISO 527-3 Sample type 2	Test speed 100 %/min.; 23 °C, 50 % r.h.
Elongation at break	175, 250	%	195	145	ISO 527-1 and ISO 527-3 Sample type 2	Test speed 100 %/min.; 23 °C, 50 % r.h.
Young´s Modulus	175, 250	N/mm²	3900	4500	ISO 527-1 and ISO 527-3 Sample type 2	Test speed 1 %/min.; 23 °C, 50 % r.h.
F5-value (stress to obtain 5% elongation)	175, 250	N/mm²	110	105	ISO 527-1 and ISO 527-3 Sample type 2	Test speed 100 %/min.; 23 °C, 50 % r.h.
THERMAL						
Shrinkage	175, 250	%	1.0	0.1	DIN 40634	150°C, 15 min.
OPTICAL						
Transparency	175, 250	%	91		ASTM-D 1003-61 method A	-
Haze	175 250	%	1.0 1.5		ASTM-D 1003-61 method A	Enlarged measurement angle
Light diffusion	175 250	cd/m² x lux	0.2 0.5		EN 167:2001, § 4.2.2	-



HOSTAPHAN®

Property	Thickness µm	Units	Value MD	Value TD	Test Method	Test Conditions
SURFACE						
Coefficient of friction (static) Treated surface/ Treated surface Treated surface/ Untreated surface Untreated surface/ Untreated surface	175, 250	-	 0.3 0.35 blocks		DIN53375 or ASTM-D 1894	-
Gloss	175, 250	-	220		DIN 67530	Measuring angle 20°
PHYSICAL/CHEMICAL						
Density	175-250	g/cm³	1.4		ASTM-D 1505-68 method C	23°C

MD = Machine direction, TD = Transverse direction

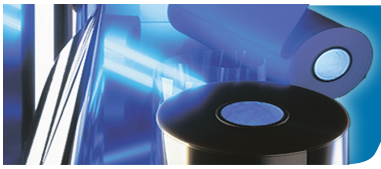
Product advantages:

- high light transmission
- distortion free view w/o die lines
- good processability
- die and laser cuttable
- cleanable with soft detergents or household glas cleaners

Delivery program Hostaphan® FACE FS1

Thickness µm	Yield g/m²	Yield m²/kg	Roll length m	Roll-diameter mm	Roll length m	Roll-diameter mm
175	245	4.1	800	475	1 600	630
250	350	2.9	600	475	1 200	650

Other roll lengths on request. Core diameter: 152.4 mm (6")



HOSTAPHAN®

Available grades:

Hostaphan® FACE FS1O: one side treated, treated side wound out

Hostaphan® FACE FS1I: one side treated, treated side wound in

Hostaphan® FACE FS1B: two side treated

The properties shown in this technical data sheet only apply to the film itself. We cannot guarantee the properties of an intermediate or final product made from or using the film. Instead, the intermediate or final product must be subjected to standard industrial testing.

This data sheet reflects our state of knowledge at the time this was prepared. The purpose is to provide an overview of the characteristics of our products and their potential uses. The values given reflect the typical characteristics of the film. They are not specification limits. They are neither a guarantee of specific properties nor the suitability of products in specific applications. The user must observe industrial property rights, such as patents or trademarks. The quality of our products is covered by the terms of the General Conditions of Sale of MITSUBISHI POLYESTER FILM GmbH.

Edition 05/20

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Product Information

DuPont Teijin Films

Melinex®

Polyester Films

Melinex® FS1

Product Description

Melinex® FS1 is a sparkling optically clear knurled film with an antistatic coating on the inside surface providing a limited level of anti-fog performance and an adhesion promoting pretreatment on the outside.

Typical Applications

Melinex® FS1 can be used for disposable medical faceshields and visors where its excellent clarity and anti-fog properties are utilised. Melinex® FS1 is available in thicknesses of 125, 175 and 250 micron.

General Information

Melinex® FS1 can withstand a broad range of temperatures and has good resistance to moisture and most chemicals. As per Article 3(3) of the REACH regulation (EC) No 1907/2006 Melinex® FS1 film is classified as an article. There are no substances intended to be released from the above film under normal, reasonably foreseeable conditions of use, as defined by Article 7(1).

Food Contact Advice

Melinex® FS1 has not been assessed against Food Contact Legislation

Film Properties

Property	Unit	Typical Values			Test Method
General		**125**	**175**	**250**	
Thickness	micron	125	175	250	DTF Method
Area Yield	m²/kg	5.7	4.0	2.9	DTF Method
Relative Density		1.4	1.4	1.4	Based on ASTM D1505-79
Electrical		**125**	**175**	**250**	
Surface Resistivity	log ohms / square	10	10	10	DTF Method
Mechanical		**125**	**175**	**250**	
Tensile Strength at Break - MD	kgf/mm²	17.5	17.5	17.5	Based on ASTM D882-83
Tensile Strength at Break - TD	kgf/mm²	17.5	17.5	17.5	Based on ASTM D882-83
F5 (force to elongate 5% of gauge range) - MD	kgf/mm²	10	10	10	Based on ASTM D882-83
F5 (force to elongate 5% of gauge range) - TD	kgf/mm²	10	10	10	Based on ASTM D882-83
Optical		**125**	**175**	**250**	
Haze	%	1.0	1.0	1.5	Based on ASTM D1003-77
Total Luminous Transmission (TLT)	%	89	89	88	Based on ASTM D1003-77
Thermal		**125**	**175**	**250**	
Upper Melt Temperature	C	255-260	255-260	255-260	Based on ASTM E794-85
Coefficient of Thermal Expansion (between 20 to 50C)	ppm/K	19	19	19	Based on ASTM E831-06
Shrinkage (after 5 mins at 150C) - MD	%	1.2	1.2	1.2	Based on ASTM D1204-78
Shrinkage (after 5 mins at 150C) - TD	%	0.5	0.5	0.5	Based on ASTM D1204-78

Disposal Advice

Disposal of Melinex® FS1 does not present special disposal problems. Where waste occurs in a clean, uncontaminated form it can be recycled. In most circumstances, once Melinex® FS1 has been laminated, coated, printed or metallised, incineration with Energy Recovery is the most environmentally efficient recovery route. Melinex® FS1 can also be burned in an incinerator with normal refuse or can be buried as a relatively inert material in a landfill. The disposal method should comply with appropriate local and country regulations.

Date of Last Revision: 01 Apr 2020

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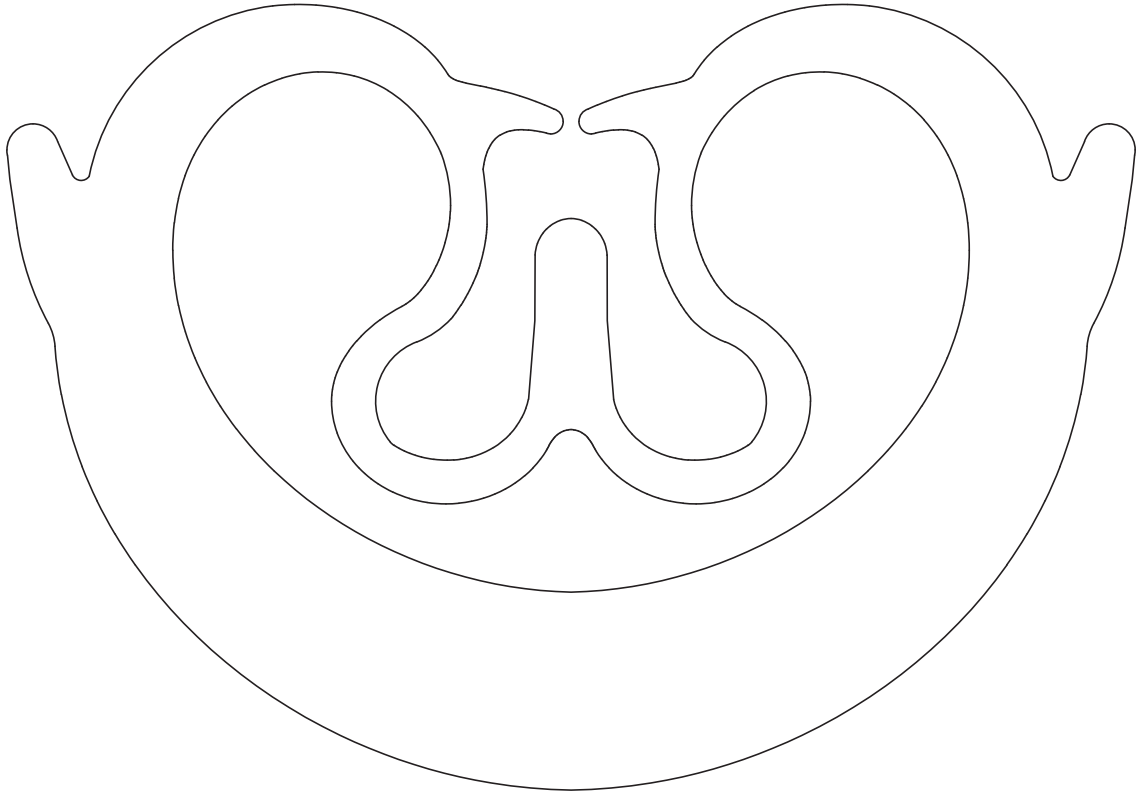
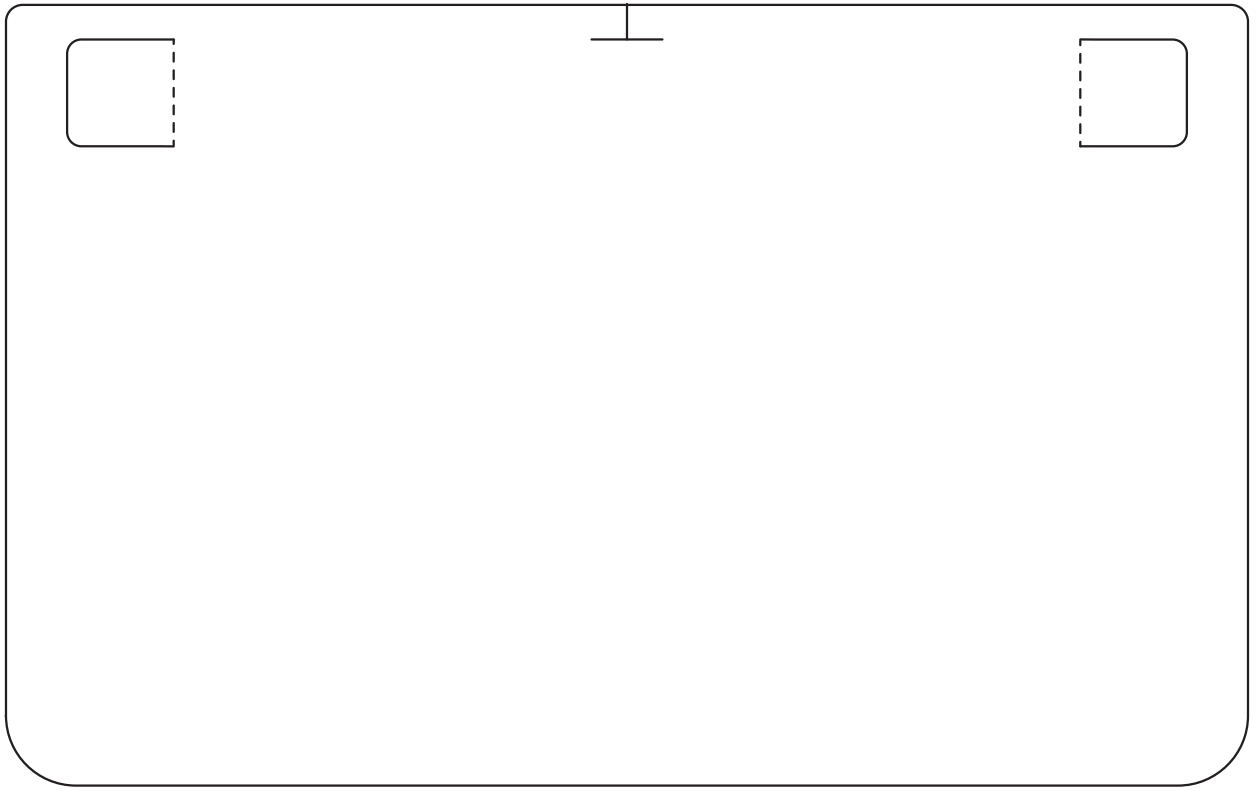


APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:	07/05/20	RFC+001 REV A	Ramfoam Care+ Headpiece	

APPENDIX 03



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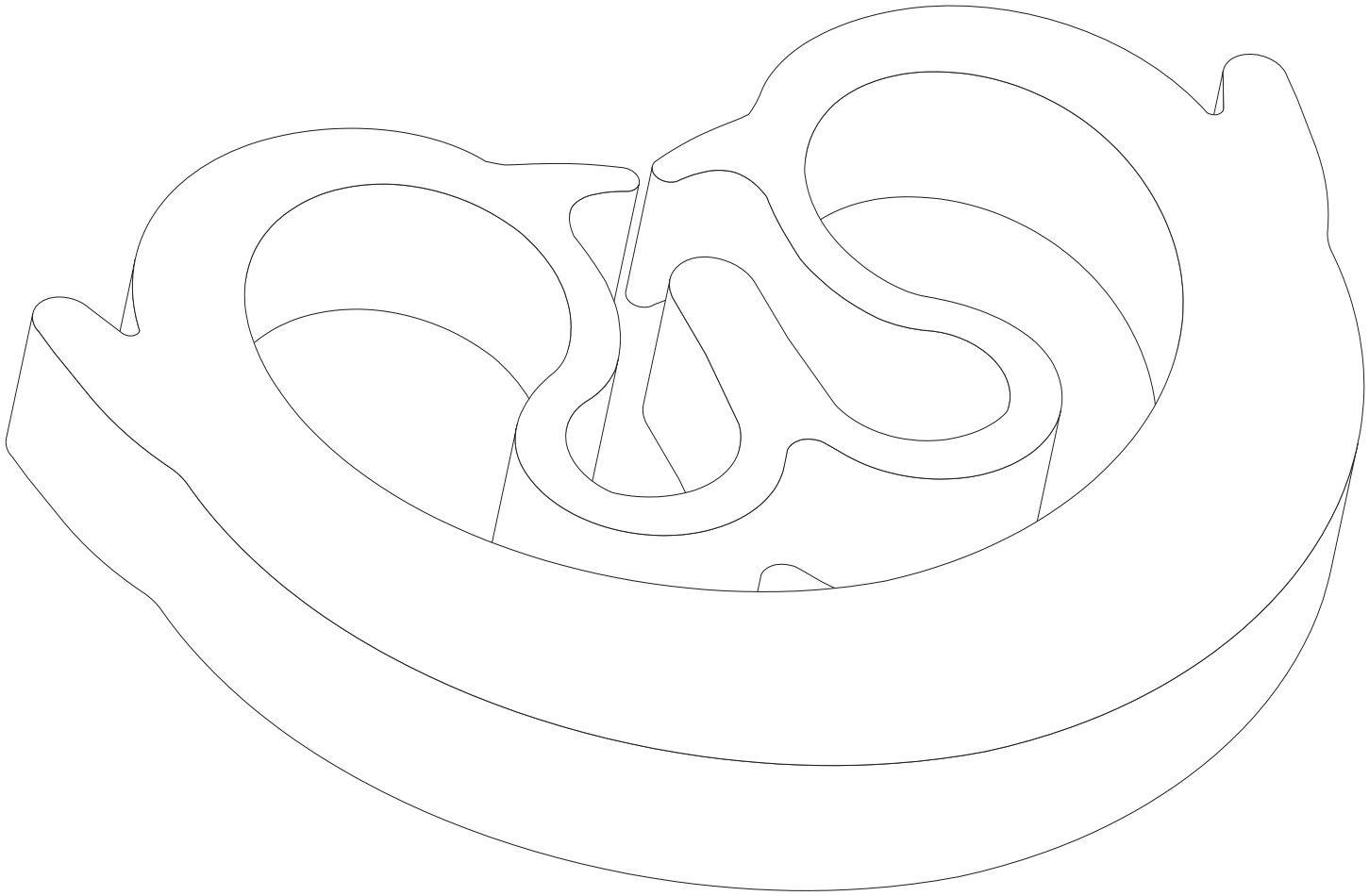
APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:	07/05/20	RFC+002 REV A	Ramfoam Care+ Visor	

APPENDIX 03



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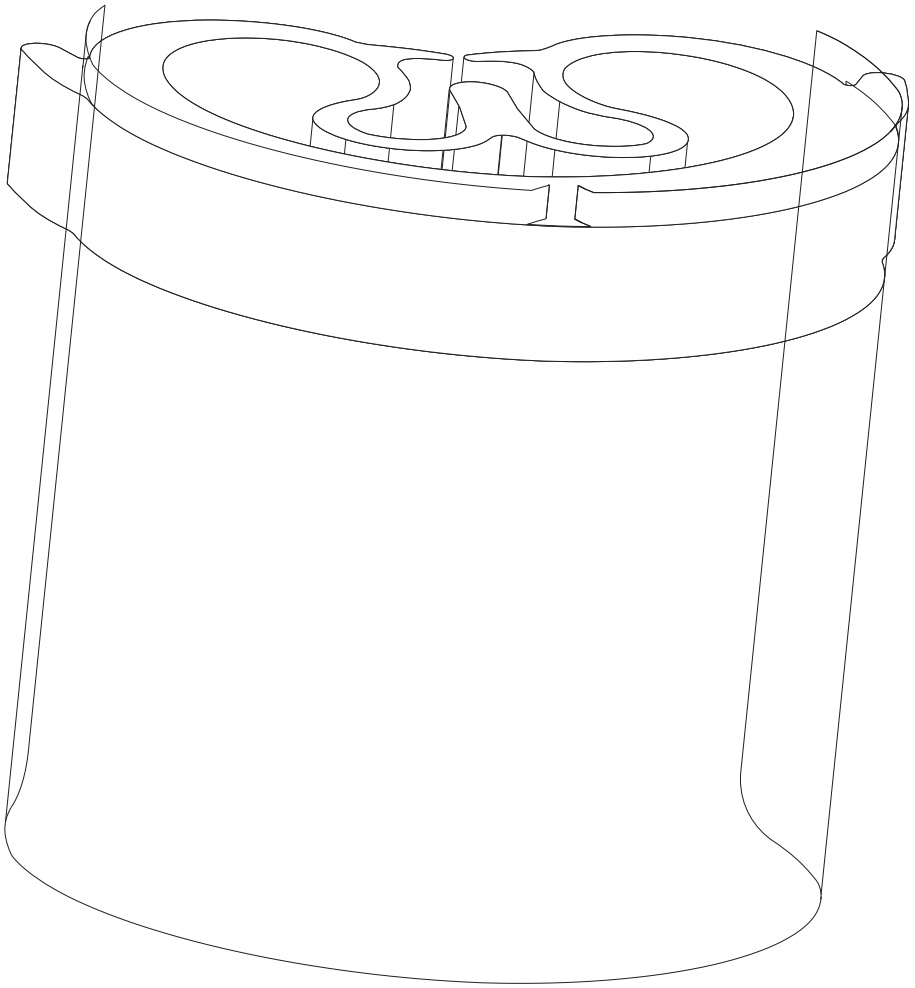
APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:	07/05/20	RFC+003 REV A	Ramfoam Care+ 3D Render Headpiece	

RAMFOAM ENGINEERING INNOVATION

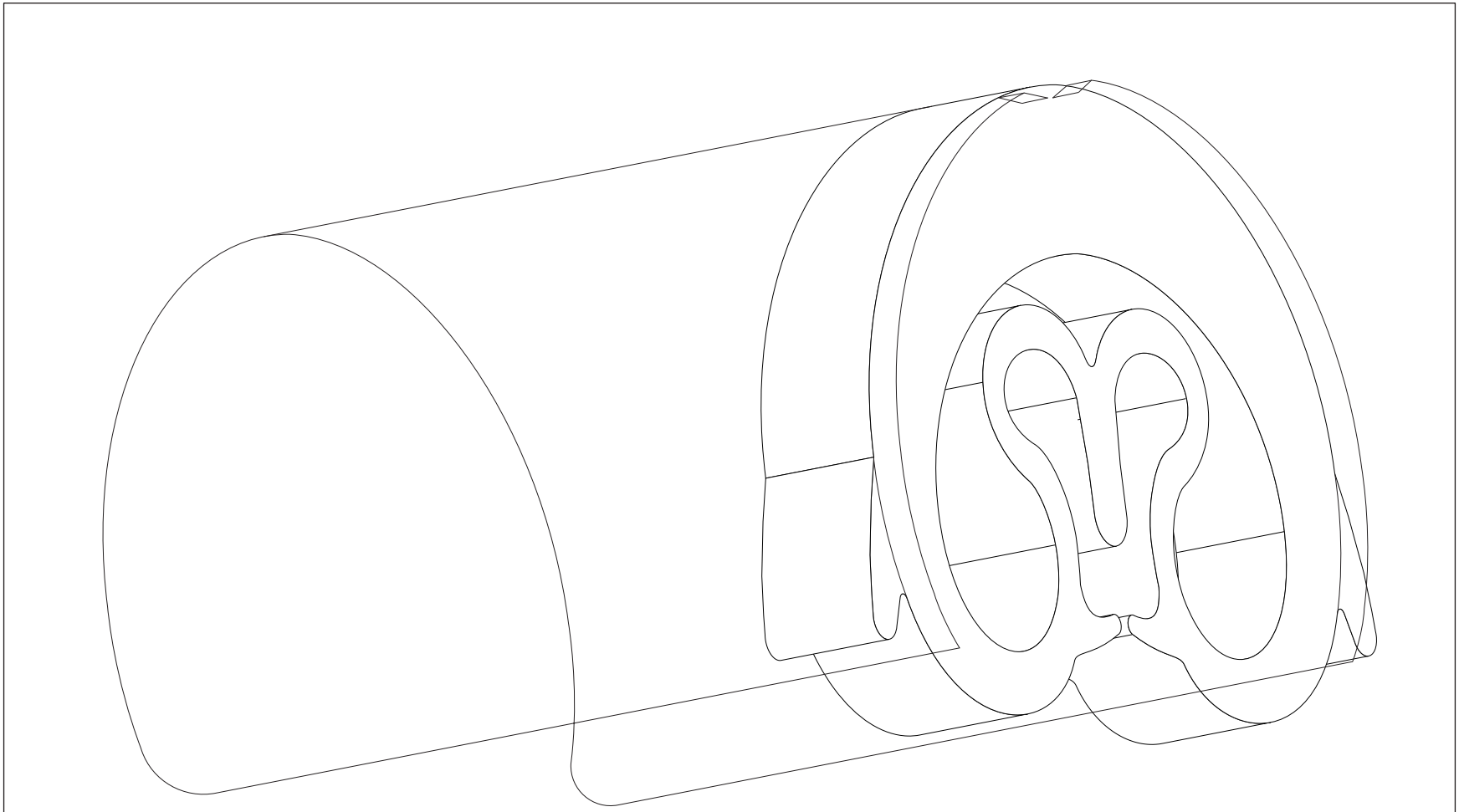
RAMFOAM care

APPENDIX 03



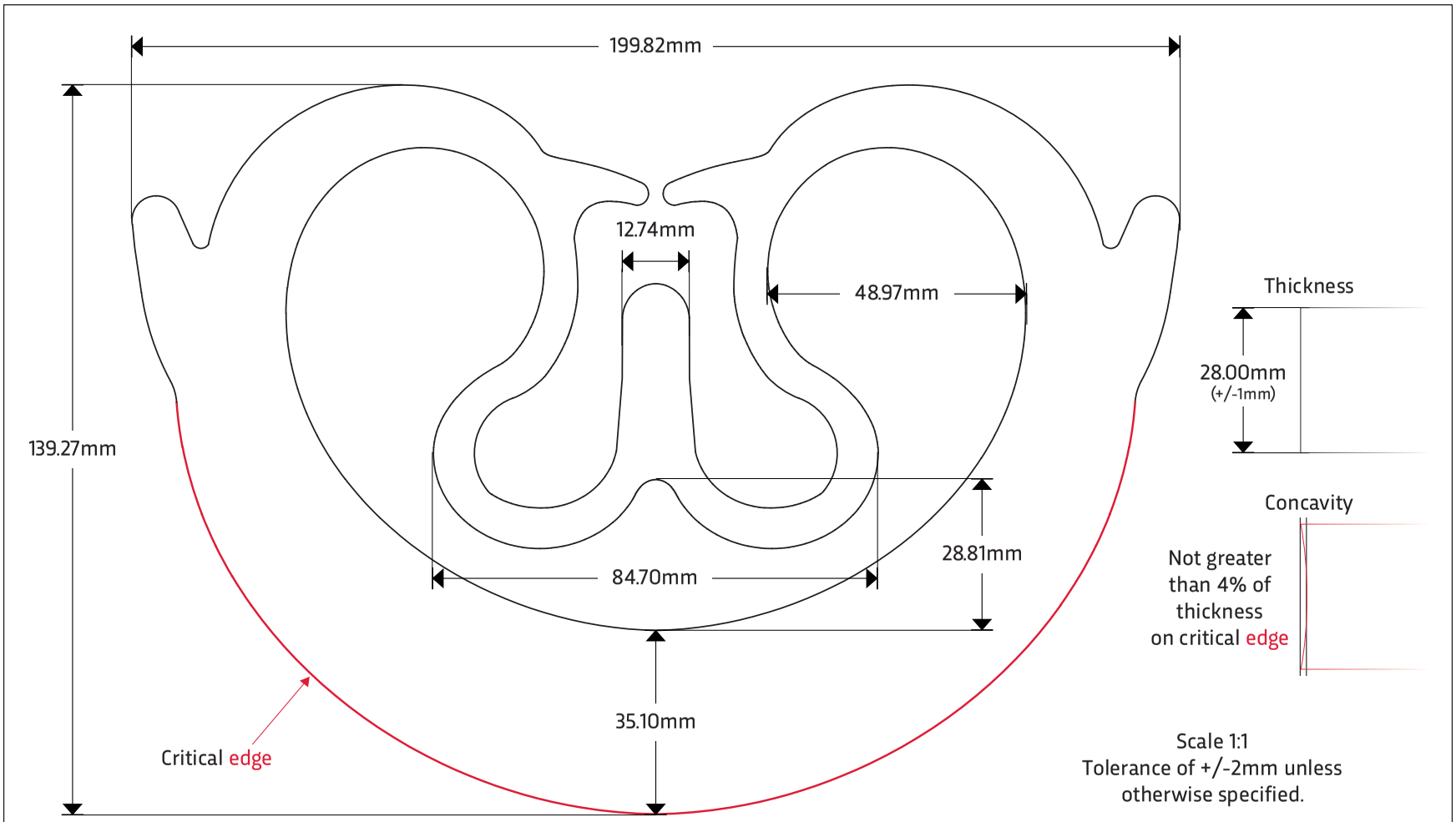
APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:	12/05/20	RFC+004 REV A	Ramfoam Care+ 3D Render Assembled	

APPENDIX 03



APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:	13/05/20	RFC+005 REV A	Ramfoam Care+ 3D Render Assembled	

APPENDIX 03



APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	
	SIGNATURE:	28/05/20	RFC+007 REV B	Ramfoam Care+ Headpiece Dimensions	RAMFOAM ENGINEERING INNOVATION

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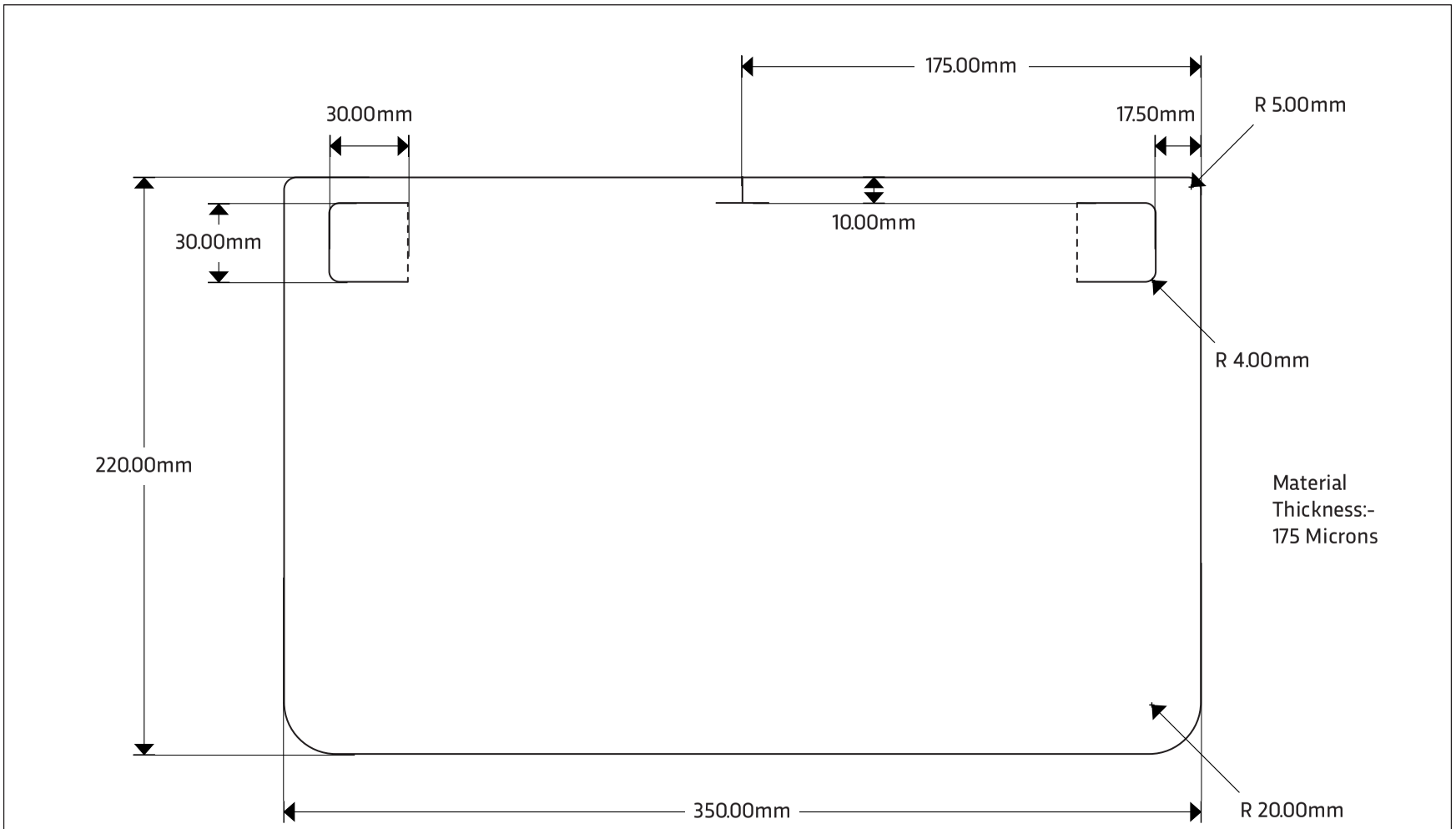

APPROVAL	PRINT NAME:	DATE:	DRAWING REF	DRAWING TITLE	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:	16/07/20	RFC+008 REV C	Ramfoam Care+ Visor Dimensions	

APPENDIX 03

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MY NAME IS:-

CE 2777 (EU) 2016/425

www.ramfoamprotect.com

APPROVAL	PRINT NAME:	DATE: 13/07/20	DRAWING REF RFC+009 REV A	DRAWING TITLE Ramfoam Care+ Label	RAMFOAM ENGINEERING INNOVATION
	SIGNATURE:				

APPENDIX 03

RAMFOAM ENGINEERING INNOVATION
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EN 166:2001

RAMFOAM LTD

A privately owned British SME with manufacturing sites in the heart of the UK and Dubai, UAE. For 25 years we have built a reputation as the market leader in the conversion of Polyethylene (PE) foam. Ramfoam Ltd are the largest global converter of Azote PE foam (Plastazote®).

Plastazote® is manufactured in the UK by Zotefoams through a unique process that makes it inert, pure, lightweight and durable. Acknowledged as the most cited thermoplastic foam material in medical literature.

THE 'RAMFOAM CARE+'

Due to its unique registered design, choice of materials and world class manufacture, the Ramfoam Care+ is transforming and setting new standards within the Protective Visor Market.

The simplistic two part patent pending design, of headpiece and optically clear visor offers considerable technical and commercial advantages against the numerous visor designs currently available in the market.

It's made of two components:-

- **Plastazote® Foam Headpiece.**
- **Optically Clear Visor.**

Both components combine for a very simple and straightforward, self-assembly kit that literally takes seconds to assemble and thus frees up valuable storage and transportation opportunities.

The technical advantages of the Ramfoam Care+ :-

- **Certification to EN 166:2001.**
- **Lightweight - just 32 grammes.**
- **Reusable - Plastazote® foam headpiece can be cleaned with soap and water, disinfected or sterilised.**
- **Comfort - Plastazote® medically approved PE foam offers the optimum and safe wearer comfort use ability, promoting user well being and convenience.**
- **Recyclable - The two constituent materials are both recyclable materials.**
- **Cost Effective - The re-usability of the headpiece means the cost of the replacement clear visor over the lifetime, makes it one of the most cost effective options on the market.**
- **Environmental Impact - Reduces supply chain carbon footprint by lower volumetric shipments.**
- **Lower Storage and Transportation Costs - The two part self assembly results in a compact finished packed product.**
- **Made In Britain - Raw materials are made in the UK, with the completed unit manufactured at our Tividale site in the Midlands.**

RAW MATERIALS

Plastazote® is a latex free, non toxic and hypo-allergenic closed cell foam. The use of Plastazote® foams helps reduce skin irritation when in direct contact. Plastazote® foams are typified by their highly consistent cell structure. The unique manufacturing process results in a highly repetitive finished quality products.

Ramfoam Care+ uses a optically clear material with an antistatic coating, providing a level of anti-fog performance.

Well established recycling routes exist nationally to transform end of life products into new and creative products.

Ramfoam Ltd
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UK MANUFACTURED

nqa ISO 9001 QUALITY MANAGEMENT

APPENDIX 04

RAMFOAM
ENGINEERING INNOVATION

RAMFOAM care

EN 166:2001

WITH CARE AND COMFORT AT THE HEART OF EVERY DESIGN

Foam based personal protection solutions, proudly manufactured at our UK-based facility in the West Midlands. Designed with the wearer in mind, to outperform alternatives and at lower whole life costs.

REUSABLE, SELF-ADJUSTING COMFORT FIT HEADPIECE

Medically approved skin contact foam, manufactured from Zotefoams market-leading Plastazote®.

The design provides a comfort, self-adjusting fit and can be reused, time and again.

Its closed-cell structure doesn't allow the ingress of liquids or aerosols, preventing the harbouring of bacteria. Because all liquids are restricted to the surface, disinfecting and sterilisation can be performed easily.

REPLACEABLE, OPTICALLY CLEAR PROTECTIVE VISOR

Ramfoam Care+ is manufactured with an anti-static and anti-fog coated visor.

Extending from the forehead to below the chin and wrapping around the sides of the face to provide protection to the complete facial area.

The most vulnerable facial areas, such as eyes, nose and mouth are protected from splashing or spraying.

EASY ASSEMBLE, LIGHT WEIGHT TWO PIECE DESIGN

Setting new standards within the market place.

The primary goal of the Ramfoam Care+ is to provide maximum protection without compromising on comfort.

A self-assembly kit of just two components that literally takes seconds to assemble.

Built-in face mask harness points, to reduce ear injury by other PPE products.

Easy clean white label with name tag area.

MEDICAL GRADE FOAM

Closed cell cross-linked polyethylene foams, such as Plastazote® foam and Evazote® foam, are widely used in sports and medical markets. Their closed cell structure prevents the ingress of sweat and other liquids and aerosols which can harbour bacterial growth resulting in unpleasant smells. Any liquid is restricted to the surface where it is easily cleaned with soap and water or disinfected or sterilised with common agents such as IPA or hypochlorite solution. For use where long-term repeated skin-contact is necessary, the easily cleaned closed-cell foams are more suitable than the open-cell foam alternative.

SUPPORTING THE NHS

Ramfoam Ltd will make donations of the Ramfoam Care+ visors to the NHS and front-line workers as part of every order received.

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nqa ISO 9001 QUALITY MANAGEMENT

APPENDIX 04

RAMFOAM CARE+

Product Safety, Quality & Hygiene Procedures Manual

3. Product Safety and Quality Management

Issue No: 1
Date: 04.07.2016
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3.1 Product safety and quality management system

Ramfoam Care+ processes and procedures to meet the requirements of the *Standard* shall be documented to allow consistent application, facilitate training, and support due diligence in the production of a safe and legal product.

This Product Safety, Quality & Hygiene Procedures Manual (PSQHPM) contains an outline and details of the working methods, systems and procedures and/or references to where such an outline and /or details are documented. The manual shall be navigable, readily available to key employees and translated into appropriate languages, where appropriate. Documents shall be clearly legible, unambiguous and sufficiently detailed to enable their correct application by appropriate employees. The system shall be fully implemented, reviewed at appropriate planned intervals and improved where necessary.

3.2 Documentation control

An effective document control system shall ensure that only the correct versions of documents, including recording forms, are available and in use.

All controlled documents and forms in use shall be clearly identified, properly authorised and be the correct version. Documents shall be clearly legible, easily understood and readily accessible to relevant employees at all times. It is the responsibility of the Quality Manager to ensure that all procedures and documents within this manual are the current version and correctly authorised. Any amendments to procedures and/or documents must be authorised and recorded by the Quality Manager, ensuring that all obsolete procedures and/or documents have been rescinded.

All obsolete procedures and/or documents shall be removed from this manual by the Quality Manager. The new version of the document and/or procedure shall be inserted in place of the obsolete version and the *Amendment Record* amended to accurately reflect these changes. Where documents and records are in electronic form, they shall be suitably protected to prevent loss or malicious intervention.

3.3 Record keeping

Ramfoam Care+ shall maintain genuine records to demonstrate the effective control of product safety, legality and quality.

Records, including process and production documentation, shall be legible, genuine, authorised, retained in good condition and retrievable for a minimum of 3 years. Where records are in electronic form, they shall be suitably backed up to prevent loss. Any alterations to records shall be authorised, with the justification for the alteration documented. Senior management shall ensure that all records relating to product safety, legality, regulatory compliance and quality are organised, maintained, appropriately stored and available for retrieval.

Ramfoam Care+

Product Safety, Quality & Hygiene Procedures Manual

3. Product Safety and Quality Management

3.4 Specifications

Ramfoam Care+ shall ensure that appropriate specifications exist for raw materials, intermediate and finished products, and any product or service which could affect the quality of the finished product and customer requirements.

Specifications for raw materials, including product packaging, and finished goods are established and maintained to ensure suitability of materials for direct food contact. Specifications should be accurate, ensure compliance with relevant safety and legislative requirements and, where appropriate, be formally agreed between the supplier and Ramfoam Care+.

Where product characteristics change the specification shall be reviewed and re-issued if necessary. Raw material and finished goods specifications are reviewed annually to ensure continued compliance with relevant safety and legislative requirements and suitability for direct food contact. Where specifications are in electronic form, they shall be suitably protected to prevent loss or malicious intervention.

Declarations of compliance for each material type shall be maintained, which enables customers to ensure compatibility with the product with which materials may be in contact. As a minimum, the declaration of compliance shall contain the nature of the material used in the manufacture of the product, confirmation that the material meets relevant legal requirements, the inclusion of any post-consumer recycled materials and shall identify any limitations of use of the product.

Appendices
3.4.A – *Raw Material Specification*
3.4.B – *Supplier Packaging Specification*
3.4.C – *Supplier Specification*
3.4.D – *Product Specification Sheet*
3.4.E – *Declaration of Compliance - R*
3.4.F – *Supplier Packaging Specification (NDC)*
3.4.G – *Declaration of Compliance - NR*

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3.5 Internal audits

Ramfoam Care+ shall demonstrate that it verifies the effective application of the requirements of the *Standard* through internal audits.

All methods, systems and procedures within the PSQHPM shall be internally audited annually, as a minimum. Audits shall be planned and their scope and frequency established in relation to the risks associated with the activity and previous audit performance. Internal audits shall be conducted by appropriately trained competent auditors, nominated by the Quality Manager, whom, to ensure impartiality, are sufficiently independent from the process being audited.

Internal audit reports shall be sufficiently detailed to ensure that conformity, as well as non-conformity, can be clearly identified and verified. Non-conformities observed during audits shall be notified to the employees responsible for the process being audited. Root cause analysis shall be used to determine appropriate corrective actions and those actions implemented within a specified and appropriate timescale. Close-out of corrective actions shall be verified and recorded. Audits shall be documented on correct and authorised versions, as retained within the PSQHPM.

Appendices
3.5.A – *Monthly Quality & Hygiene Audit – 1 – Primary*
3.5.B – *Monthly Quality & Hygiene Audit – 2 – Secondary*
3.5.C – *Production Order Work Sheets Audit*
3.5.D1 – *Quarterly Hygiene Audit Report – Primary*
3.5.D2 – *Quarterly Hygiene Audit Report – Secondary*
3.5.E – *Audit Report Form*
3.5.F – *Audit Report Form Continuation Sheet*
3.5.G – *Audit Non-Conformance Report (NCR)*
3.5.H – *Non-Conformance Root Cause Analysis Form*

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3.6 Supplier approval and performance monitoring

Ramfoam Care+ shall operate procedures for approval and monitoring of its suppliers. This shall include suppliers of materials and services and ensure that materials and services procured conform to defined requirements.

Suppliers to Ramfoam Care+ shall be evaluated and selected based on their ability to supply materials, products and services in compliance with the company's requirements. This shall include suppliers of raw materials, product packaging, subcontracted processes, transport, and finished product.

Suppliers are evaluated based on one or more of:

- BRC Certification
- Supplier Questionnaire
- Site audit
- Inspection and monitoring of delivered goods and/or materials.

Results of supplier evaluations are documented on a *Supplier Evaluation Form* and suppliers whom have been approved are awarded a place on the *Approved Supplier List* and given a 'Supplier Rating' as defined below:

A Suppliers of direct food contact materials and products who hold a current certificate of accreditation to the BRC Global Standard and who have demonstrated their ability to consistently supply materials, products and services in compliance with Ramfoam Care+' requirements.

B Suppliers of direct food contact materials and products who hold a current certificate of accreditation to the BRC Global Standard but who have been unable to consistently supply products and services in compliance with Ramfoam Care+' requirements.

C Suppliers of direct food contact materials and products who do not currently hold a current certificate of accreditation to the BRC Global Standard but have either indicated and demonstrated their intentions to gain accreditation to the Standard or whose evaluation is deemed satisfactory.

D Suppliers of non-direct food contact materials and products. Although preferred, it is not essential that suppliers within this category hold a current certificate of accreditation to the BRC Global Standard.

Supplier performance shall be monitored and suppliers shall be reviewed and evaluated on an annual basis to ensure continued compliance in line with the 'Supplier Rating'.

In exceptional circumstances the Production Director can authorise the sourcing of raw materials, product packaging, transport finished product and/or services from suppliers who are not currently on the approved supplier list. On these occasions the supplier approval procedure shall be implemented within an appropriate timescale.

Appendices
3.6.A – *Supplier Self-Assessment Questionnaire*
3.6.B – *Supplier Audit Report*
3.6.C – *Supplier Evaluation Form*
3.6.D – *Approved Supplier List*

3. Product Safety and Quality Management

3.7 Management of subcontracted processes

Where any process steps in the manufacture of products are subcontracted to a third party or undertaken at another site, Ramfoam Care+ shall ensure this does not compromise the quality, safety or legality of the product.

Subcontracting of production is only awarded to suppliers whom are themselves accredited to the BRC Global Standard. In exceptional circumstances, suppliers whom are not accredited shall be considered only following assessment by the Production Director and the Quality Manager to ensure that technical standards are appropriate and effectively audited and documented. Subcontractors shall be evaluated and awarded a 'supplier rating' as defined in 3.6.

Subcontracting of production shall be in agreement with customers whose product is to be subcontracted. The use of subcontractors and the status of the subcontractor with respect to the *Standard* shall be notified to the customer by letter and/or e-mail. Clear specifications shall be agreed for all work outsourced to a subcontractor and controls shall be in place for checks on finished work to ensure the safety and quality of product manufactured meets specification.

3.8 Management of suppliers of services

Ramfoam Care+ shall ensure that where services are outsourced, the service is appropriate and any risks presented to product safety, quality or legality have been evaluated to ensure effective controls are in place.

Suppliers of services shall be evaluated and selected based on their ability to supply services in compliance with the company's requirements. Such services may include, but are not limited to, pest control, laundry services, transport & distribution, storage & dispatch, sorting or rework, laboratory services, calibration services and waste management.

Suppliers shall be evaluated based on one or more of:

- BRC Certification
- Supplier Questionnaire
- Site audit
- Inspection and monitoring of delivered goods and/or materials.

Results of supplier evaluations shall be documented on a *Supplier Evaluation Form* and suppliers whom have been approved are awarded a place on the *Approved Supplier List* and given a 'Supplier Rating' as defined within section 3.6. Suppliers of services shall be reviewed and evaluated on an annual basis to ensure continued compliance in line with the 'Supplier Rating'.

Documented agreements shall exist with suppliers of services which clearly define service expectations and ensure potential risks associated with the service have been addressed.

In exceptional circumstances the Production Director can authorise the sourcing of services from suppliers who are not currently on the approved supplier list. On these occasions the supplier approval procedure shall be implemented within an appropriate timescale.

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3.9 Traceability

Ramfoam Care+ shall be able to trace and follow all raw materials through processing to the distribution of product to the customer and vice versa.

Established systems and procedures shall be in place to ensure the ability to trace all raw materials from the supplier through all stages of processing and distribution of finished product and vice versa. Identification of raw materials, intermediate products, finished products, non-conforming product and quarantined goods shall be adequate to ensure traceability. Where product screening or any reworking operation is conducted, traceability shall be maintained.

To ensure traceability of finished product held in stock or delivered to a customer, the following information, as a minimum, must be incorporated onto all finished product outer carton labels:

Customer
Production Order Number
Outer Carton Number
Production Date

The traceability systems in place shall be tested annually, as a minimum, to ensure traceability can be determined from raw materials to finished product and vice versa.

Ramfoam Care+

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3.10 Customer focus and contract review

Senior management shall ensure that processes are in place to determine customer needs and expectations with regard to quality, safety and legality, and ensure these are fulfilled.

Communication with customers shall be either by site visits, telephone and/or e-mail communication. The job titles responsible for communication are:

- Technical Director
- Sales Director
- Commercial Manager
- Sales Executive
- Production Planner
- Logistics Administrator
- Quality Manager
- Accounts/Office Manager

The Sales Director, Commercial Manager and Sales Executives shall ensure customer needs and requirements are reviewed on an ongoing basis and any changes to existing agreements or contracts shall be agreed, documented and communicated to the planning, production, quality, warehouse and logistics departments.

Wherever possible, customer enquiries shall be advised to the Technical Manager by completing a *Customer Enquiry Form.* Prior to manufacture a product specification shall be prepared and, where possible, agreed with the customer and customer approved samples shall be retained for future reference.

All customers orders received shall be processed through the 'LeeMa' management system and production documentation produced from which the customer's order shall be manufactured. Where customers have set particular product performance criteria, these shall be included within the quality standards for the product and included within production documentation.

Customer product stock levels shall be maintained and advised to the customer at a frequency determined by each individual customer. To ensure customer requirements are fulfilled, customer service levels shall be monitored and reviewed. 'On time in full' deliveries (OTIF) shall be monitored and reviewed annually along with customer complaints. Where and when appropriate a periodic customer survey shall be implemented.

Appendices
3.10.A – *Customer Enquiry Form*

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3.11 Complaint handling

Ramfoam Care+ shall ensure that customer complaints, relating to product hygiene, safety or quality, shall be handled effectively and the information used to reduce complaint levels.

All customer complaints shall be recorded and investigated, including root cause analysis, and the results of the investigation documented on a *Customer Complaint Form*. Actions appropriate to the seriousness and frequency of the problems identified shall be carried out promptly and effectively by appropriately trained employees, overseen by the Quality Manager or Production Director. Based on the results of the investigation, corrective and preventative measures shall be established and fully implemented into working practices, procedures and/or systems. The Quality Manager shall manage customer complaint handling and ensure effective close out of complaints.

An analysis of complaints shall be conducted annually, as a minimum, to identify significant trends and to implement ongoing improvements and any corrective and/or preventative actions required. Where there has been an increase or repetition of a complaint type, root cause analysis shall be used to implement ongoing improvements to product safety, legality and quality, and to avoid recurrence. This analysis shall be made available to relevant employees.

Appendices
3.11.A – *Customer Complaint Form*
3.11.B – *Customer Complaint Analysis*

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3.12 Management of product withdrawals, and incidents and product recalls

Ramfoam Care+ shall have a plan and systems in place to effectively manage any product withdrawals or returns from customers, incidents and product recalls to ensure that all potential risks to the hygiene, quality, safety or legality of products and the final consumer are controlled.

3.12.1 Product withdrawals

A documented product withdrawal procedure shall be implemented and, as a minimum, shall include:

- identification of the key employees involved in assessing potential product withdrawals or returns, with their responsibilities clearly defined
- a communications plan, including methods of informing customers
- root cause analysis and corrective action to implement appropriate improvements as require

The product withdrawal procedure shall:

- be capable of being operated at any time
- ensure notification to relevant customers and suppliers
- ensure the return of identified stocks
- take account of the logistics for return of the recalled product
- ensure suitable storage of returned product
- ensure suitable review and disposal of returned product

Following on from the implementation of a product withdrawal, the Quality Manager is responsible for ensuring that root cause analysis is used to determine and implement appropriate preventative actions and improvements as necessary.

To ensure effectiveness, the product withdrawal procedure shall be tested annually, as a minimum, with the results documented and retained for inspection, including timings of key activities. The results of the test, and of any actual withdrawals, shall be used to review the procedure and implement improvements as necessary.

Ramfoam Care+

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3.12 Management of product withdrawals, and incidents and product recalls (continued)

3.12.1 Product withdrawals (continued)

Product withdrawal procedure

Step	Task	Method	Location of information
1	Shift Manager to immediately inform the Quality Manager or Production Director of site incident, customer complaint or supplier notification of issue.	Contact by internal phone system during 'A' shift or by mobile phone during 'B' or 'C' shifts.	List of employee contact numbers displayed within Planning Office & Print Room (Primary) and Production Office (Secondary).
2	QM or PD to establish and identify relevant stakeholders and location of product.	Examine production records and stock records.	Production records and stock records held within Planning Office (Primary). Location of product identified within 'LeeMa' stock database.
3	QM or PD to notify all relevant customers of the recall within 24 hours and arrange return of relevant product.	Contact by phone or e-mail.	Customer contact details held within production records within Planning Office (Primary).
4	QM or PD to arrange transport and return of recalled product.	Contact an approved transport haulage company.	Contact details of approved transport contractors are displayed within the Planning Office (Primary).
5	QM or PD to inform Warehousing & Logistics Manager of the requirement to quarantine withdrawn product when returned to site.	Contact by internal e-mail.	Internal e-mail network.
6	QM or PD review product withdrawal issue and conduct root cause analysis and establish corrective & preventative actions, method of disposal, if necessary, and implement appropriate improvements as required.	Internal management meeting.	N/a

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Product Safety, Quality & Hygiene Procedures Manual

3. Product Safety and Quality Management

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3.12 Management of product withdrawals, and incidents and product recalls (continued)

3.12.2 Incidents

Site incidents, especially those affecting product safety and/or quality, shall be reported, recorded and documented on an *Incident Form*. The Quality Manager shall investigate the incident, establish corrective and preventative actions and record all findings & actions.

Written guidance shall be provided for employees as to the types of events that would constitute an "Incident". These are:

- damage to the machine and/or tooling resulting in any form of metal contamination.
- all glass or plastics breakages within the production and/or storage areas.
- damaged or broken knives or blades observed or found within the production or storage areas.
- any oils or water spillages likely to contaminate raw materials, work- in-progress or finished goods.
- any form of personal injury to employees likely to contaminate raw materials, work-in-progress or finished goods.
- any form of pest migration into the production or storage areas likely to contaminate raw materials, work-in-progress, or finished goods.

Incidents shall be reviewed annually, as a minimum, and the Quality Manager shall ensure preventative actions are taken when appropriate based on the review.

Should an incident be deemed to have potentially affected product already delivered to the customer, the 'product withdrawal procedure' must be implemented.

Incidents must be reported by the Shift Manager or Shift Supervisor to the Quality Manager or, in his absence, the Production Director. Where necessary, the Quality Manager shall report the incident to the Production Director. Where safety or quality of product may have been affected, stock holding shall be quarantined to prevent release of product. Relevant stakeholders shall be notified within 24 hours and recall of product effected in a suitable time scale determined by the Quality Manager or Production Director. The timescale shall be determined dependant on the nature and/or severity of the issue.

Appendices
3.12.A – *Incident Form*

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3.12 Management of product withdrawals, and incidents and product recalls (continued)

3.12.3 Product recalls

A procedure to manage product recalls, initiated by a customer, shall be documented and, as a minimum, shall include:

- identification of the key employees involved in assessing potential product recalls, together with clearly defined responsibilities
- a communications plan that includes methods of informing customers and, where necessary, regulatory bodies, in a timely manner
- corrective actions and business recovery
- review of any recalls in order to conduct root cause analysis and implement appropriate improvements as required

Where products are involved in a customers product recall, the Quality Manager, or Production Director in his absence, shall assist the customer with the provision of relevant information, including traceability, as required.

Product recall procedure

Step	Task	Method	Location of information
1	Quality Manager or Production Director to inform relevant employees following notification from a customer of a product recall involving Ramfoam Care+ product.	Contact by e-mail and assessing during daily production meeting.	List of employee e-mail addresses displayed within Planning Office (Primary).
2	QM or PD to establish and identify relevant traceability information and details of product supplied.	Examine production records and stock records.	Production records and stock records held within Planning Office (Primary). Details of product supplied held within 'LeeMa'.
3	QM or PD to advise customer, and where necessary, regulatory bodies, of all relevant product details of affected product.	Contact by phone or e-mail.	Customer contact details held within production records within Planning Office (Primary). Regulatory bodies' details found via internet.
4	QM or PD to organise corrective action, implement product withdrawal procedure, if necessary, withdraw product from affected customer and/or organise replacement product if required.	Contact by phone or e-mail.	Customer contact details held within production records within Planning Office (Primary).
5	QM or PD and management team to review product recall issue and conduct root cause analysis to establish preventative actions and implement appropriate improvements as required.	Internal management meeting.	N/a

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Customer details: Ramfoam Limited
Lower City Works
Hainge Road
Tividale
West Midlands
B69 2NR

SATRA reference: SPC0297461 /2018/2

Your reference:

Date of report: 18 May 2020

Samples received: 18 May 2020

Date(s) work carried out: 18 May 2020

TECHNICAL REPORT

Subject: Limited EN 166:2001 testing on face shield with Mitsubishi visor, described as Halo

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Daniel Harrison
Position: Business Area Manager
Department: Safety Product Testing

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Work Requested

Samples of face shields intended for medical use were received by SATRA, for testing in accordance with EN 166:2001 Personal eye-protection – Specifications.

Table 1 – Samples Received

Description	Expected Performance/Marking
Face shields intended for medical use (0.20mm clear – Mitsubishi material)	Visor marking: "xx" 1 Frame marking: "xx" EN 166 3 Where "xx" represents the identification of the manufacturer

Medical face shield - Halo

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Conclusions

Table 2

Standard	Clause / Property		Result
EN 166:2001	6	Design and manufacturing requirements	See Note A
	7.1.1	Field of vision	PASS
	7.1.2.1	Spherical, astigmatic and astigmatic refractive powers	PASS
	7.1.2.2	Transmittance	PASS
	7.1.2.3	Diffusion of light	PASS
	7.1.3	Quality of material and surface	PASS
	7.1.4.1	Minimum robustness	Not applicable
	7.1.4.2	Increased robustness	Note B
	7.1.5.1	Stability at an elevated temperature	PASS
	7.1.5.2	Resistance to ultraviolet radiation	See Note C
	7.1.6	Resistance to corrosion	Not assessed
	7.1.7	Resistance to ignition	PASS
	7.2.4	Protection against droplets and splashes of liquids	PASS

Note A: Clause not fully assessed, specifically materials not assessed for innocuousness. Manufacturer to maintain a log of the safety data sheets for each material in the event of the product being subjected to market surveillance.

Note B: Increased robustness results meet the temporary requirements for face-shields for medical use against Covid 19 as drafted by Vertical Group 3 of the European PPE Notified Bodies – see document "ECS Testing principle for COVID-19 pandemic – eye and face protectors Rev.01 from 02.04.2020. Deformation of the ocular occurred but there was no breakage. Therefore these face shields are not intended to offer any protection against mechanical impact.

Note C: Clause not assessed as products are intended for limited or single use only

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Testing

Testing was carried out in accordance with EN 166:2001.

Unless otherwise specified either in the individual test method or in this report, samples were tested 'as received', without pre-conditioning, and were tested in normal ambient conditions

Requirements

Table 3 – Permissible tolerances for refractive powers of mounted oculars without corrective effect and un-mounted oculars without corrective effect covering both eyes

Optical class	Spherical refractive power, $\frac{(D_1 + D_2)}{2}$ m^{-1}	Astigmatic refractive power, $\lvert D_1 - D_2 \rvert$ m^{-1}	Difference in prismatic refractive power cm/m		
			Horizontal		Vertical
			Base out	Base in	
1	± 0.06	0.06	0.75	0.25	0.25
2	± 0.12	0.12	1.00	0.25	0.25
3	+ 0.12 - 0.25	0.25	1.00	0.25	0.25
Note	D_1 and D_2 are the refractive powers in the two principal meridians. For optical class 3 the axes of the principle meridians shall be parallel within ± 10°				

Table 4 – Variations in luminance transmittance

Luminous transmittance		Permissible relative variation %
Less than %	Up to %	
100	17.8	± 5
17.8	0.44	± 10
0.44	0.023	± 15
0.023	0.0012	± 20
0.0012	0.000023	± 30

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Test Results

Table 5 EN 166:2001 Test Results

Clause / Test	Requirement	Test Results	UoM (See note D)	Result
6.1 Design and manufacturing requirements – General construction	Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use	All samples are free from projections, sharp edges or other defects which are likely to cause discomfort or injury to the wearer	N/A	PASS
6.2 Materials	No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation	Not assessed	N/A	PASS
6.3 Headbands	Headbands, when used as the principle means of retention, shall be at least 10 mm wide over any portion which may come into contact with the wearer's head Headbands shall be adjustable or self-adjusting	Headband width: 29mm Headband is self-adjusting	N/A	PASS
7.1.1 Field of vision (EN 168: 2001 Clause 18)	Eye-protectors shall exhibit a minimum field of vision defined by the two ellipses in EN 168: 2001 figure 13	When tested according to EN 168:2001 clause 18, no part of the defined minimum field of view was obscured by the frame	N/A	PASS

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Clause / Test	Requirement	Test Results	UoM (See note D)	Result
7.1.2.1.2 Spherical, astigmatic and prismatic refractive powers – Mounted oculars and un-mounted oculars covering both eyes (EN 167: 2001 Clause 3.2≠)	See table 3	Spherical and astigmatic refractive powers Sample / Spherical power m^{-1} / Astigmatic power m^{-1} 1L 0 0 1R 0 0 2L 0 0 2R 0 0 3L 0 0 3R 0 0 Prismatic difference Sample / Horizontal cm/m / Vertical cm/m 1 0 0 2 0 0 3 0 0	See table 6	PASS
7.1.2.2.2 Transmittance – Oculars with filtering action (EN 167: 2001 Clause 6≠)	The transmittance of oculars with filtering action shall meet the requirements given in the specific standards relating to the various types of oculars.	Sample / Luminous transmittance % 4L 88.1 4R 87.8 5L 88.2 5R 88.1 6L 88.0 6R 87.8	± 0.72 %	PASS
7.1.2.3 Diffusion of light (EN 167: 2001 Clause 4≠)	Maximum value of reduced luminance factor shall be: 1.00 $\frac{cd}{m^2 \cdot lx}$ for welding filters; 0.75 $\frac{cd}{m^2 \cdot lx}$ for oculars used in eye-protector against high speed particles; 0.50 $\frac{cd}{m^2 \cdot lx}$ for all other oculars	Sample / Reduced luminance factor / $cd.m^{-2}lx^{-1}$ 4R 0.166 4L 0.204 5R 0.232 5L 0.254 6R 0.253 6L 0.264	± 17 %	PASS

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Clause / Test	Requirement	Test Results		UoM (See note D)	Result
7.1.3 Quality of material and surface (EN 167: 2001 Clause 5≠)	Except for a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring grains, pocking, scaling and undulation	Specimen	Defects	N/A	PASS
		1	No visual evidence of defects		
		2			
		3			
7.1.4.2.2 Increased robustness – Complete eye-protectors and frames (EN 168: 2001 Clause 3.2)	On testing, the following defects shall not occur: • ocular fracture; • ocular deformation; • ocular housing or frame failure; • lateral protection failure	**Temperature**	**+55°C**	N/A	See Note B
		Left centre	OD		
		Right centre	OD		
		Left centre	OD		
		Right centre	OD		
		Left lateral	OD		
		Right lateral	OD		
		Temperature	**-5°C**		
		Left centre	OD		
		Right centre	OD		
		Left centre	OD		
		Right centre	OD		
		Left lateral	OD		
		Right lateral	OD		
7.1.5.1 Stability at an elevated temperature (EN 168: 2001 Clause 5)	Assembled eye-protectors shall show no apparent deformation	No deformation was observed		N/A	PASS
7.1.7 Resistance to ignition (EN 168: 2001 Clause 7)	No part of the eye-protector shall ignite or continue to glow after removal of the steel rod	No part of any sample ignited or exhibited any after-glow after contact with the heated rod		N/A	PASS
7.2.4 Protection against droplets and splashes of liquids	Face-shields shall cover the eye region rectangle ABCD Face shields shall have a viewing area with a minimum centre-line depth of 150 mm	Specimen	Covers rectangle ABCD	N/A	PASS
		1	Yes		
		2	Yes		
		3	Yes		
		Specimen	Centre-line depth		
		1	220 mm		
		2	220 mm		
		3	220 mm		

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Additional Information / Notes

Table 6 – Additional uncertainty of measurement information

Clause	Test / Component	UoM (see note D)
EN 167:2001 3 Spherical, astigmatic and prismatic refractive powers	Spherical and astigmatic powers	± 0.01 m^{-1}
	Prismatic difference	± 0.08 cm/m

Note D – 'UoM' denotes estimated Uncertainty of Measurement for stated test results. This uncertainty value is based on a standard uncertainty multiplied by a coverage factor k = 2, which provides for a confidence level of approximately 95%

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TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.

1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing

1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

(a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
(b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
(c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

(a) death or personal injury caused by its negligence or the negligence of its employees or agents;
(b) fraud or fraudulent misrepresentation;
(c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
(d) defective products under the Consumer Protection Act 1987; or
(e) any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

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Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

10. PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12. DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13. RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

a) hold the Goods as SATRA's bailee;

b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14. PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15. WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16. DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

b) SATRA is given a reasonable opportunity of examining such Goods; and

c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or

d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – September 2019

SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
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Tel: +44 (0) 1536 410000
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Customer details: Ramfoam Limited
Lower City Works
Hainge Road
Tividale
West Midlands
B69 2NR

SATRA reference: SPC0297461 /2018

Your reference:

Date of report: 5 May 2020

Samples received: 4 May 2020 (3rd submission)

Date(s) work carried out: 5 May 2020

TECHNICAL REPORT

Subject: Limited EN 166:2001 testing on face shield with PET visor, described as Halo

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Dave McKeown
Position: PPE Technologist
Department: Safety Product Testing

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Work Requested

Samples of face shields intended for medical use were received by SATRA, for testing in accordance with EN 166:2001 Personal eye-protection – Specifications.

Table 1 – Samples Received

Description	Expected Performance/Marking
Face shields intended for medical use (0.5 mm clear – PET)	Visor marking: "xx" 1 Frame marking: "xx" EN 166 3 Where "xx" represents the identification of the manufacturer

Medical face shield - Halo

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Conclusions

Table 2

Standard	Clause / Property		Result
EN 166:2001	6	Design and manufacturing requirements	See Note A
	7.1.1	Field of vision	PASS
	7.1.2.1	Spherical, astigmatic and astigmatic refractive powers	PASS
	7.1.2.2	Transmittance	PASS
	7.1.2.3	Diffusion of light	PASS
	7.1.3	Quality of material and surface	PASS
	7.1.4.1	Minimum robustness	Not applicable
	7.1.4.2	Increased robustness	Note B
	7.1.5.1	Stability at an elevated temperature	PASS
	7.1.5.2	Resistance to ultraviolet radiation	See Note C
	7.1.6	Resistance to corrosion	Not assessed
	7.1.7	Resistance to ignition	PASS
	7.2.4	Protection against droplets and splashes of liquids	PASS

Note A: Clause not fully assessed, specifically materials not assessed for innocuousness. Manufacturer to maintain a log of the safety data sheets for each material in the event of the product being subjected to market surveillance.

Note B: Increased robustness results meet the temporary requirements for face-shields for medical use against Covid 19 as drafted by Vertical Group 3 of the European PPE Notified Bodies – see document "ECS Testing principle for COVID-19 pandemic – eye and face protectors Rev.01 from 02.04.2020. Deformation of the ocular occurred but there was no breakage. Therefore these face shields are not intended to offer any protection against mechanical impact.

Note C: Clause not assessed as products are intended for limited or single use only

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Testing

Testing was carried out in accordance with EN 166:2001.

Unless otherwise specified either in the individual test method or in this report, samples were tested 'as received', without pre-conditioning, and were tested in normal ambient conditions

Requirements

Table 3 – Permissible tolerances for refractive powers of mounted oculars without corrective effect and un-mounted oculars without corrective effect covering both eyes

Optical class	Spherical refractive power, $\frac{(D_1 + D_2)}{2}$ m^{-1}	Astigmatic refractive power, $\lvert D_1 - D_2 \rvert$ m^{-1}	Difference in prismatic refractive power cm/m		
			Horizontal		Vertical
			Base out	Base in	
1	± 0.06	0.06	0.75	0.25	0.25
2	± 0.12	0.12	1.00	0.25	0.25
3	+ 0.12 - 0.25	0.25	1.00	0.25	0.25
Note	D_1 and D_2 are the refractive powers in the two principal meridians. For optical class 3 the axes of the principle meridians shall be parallel within ± 10°				

Table 4 – Variations in luminance transmittance

Luminous transmittance		Permissible relative variation %
Less than %	Up to %	
100	17.8	± 5
17.8	0.44	± 10
0.44	0.023	± 15
0.023	0.0012	± 20
0.0012	0.000023	± 30

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Test Results

Table 5 EN 166:2001 Test Results

Clause / Test	Requirement	Test Results	UoM (See note D)	Result
6.1 Design and manufacturing requirements – General construction	Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use	All samples are free from projections, sharp edges or other defects which are likely to cause discomfort or injury to the wearer	N/A	PASS
6.2 Materials	No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation	Not assessed	N/A	PASS
6.3 Headbands	Headbands, when used as the principle means of retention, shall be at least 10 mm wide over any portion which may come into contact with the wearer's head Headbands shall be adjustable or self-adjusting	Headband width: 29mm Headband is self-adjusting	N/A	PASS
7.1.1 Field of vision (EN 168: 2001 Clause 18)	Eye-protectors shall exhibit a minimum field of vision defined by the two ellipses in EN 168: 2001 figure 13	When tested according to EN 168:2001 clause 18, no part of the defined minimum field of view was obscured by the frame	N/A	PASS

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<table>
<tr><th>Clause / Test</th><th>Requirement</th><th>Test Results</th><th>UoM
(See note D)</th><th>Result</th></tr>
<tr><td>7.1.2.1.2 Spherical, astigmatic and prismatic refractive powers –

Mounted oculars and un-mounted oculars covering both eyes
(EN 167: 2001 Clause 3.2≠)</td><td>See table 3</td><td>Spherical and astigmatic refractive powers
<table><tr><th>Sample</th><th>Spherical power m^{-1}</th><th>Astigmatic power m^{-1}</th></tr><tr><td>1L</td><td>0</td><td>0</td></tr><tr><td>1R</td><td>0</td><td>0</td></tr><tr><td>2L</td><td>0</td><td>0</td></tr><tr><td>2R</td><td>0</td><td>0</td></tr><tr><td>3L</td><td>0</td><td>0</td></tr><tr><td>3R</td><td>0</td><td>0</td></tr></table><table><tr><th rowspan="2">Sample</th><th colspan="2">Prismatic difference</th></tr><tr><th>Horizontal cm/m</th><th>Vertical cm/m</th></tr><tr><td>1</td><td>0.1</td><td>0</td></tr><tr><td>2</td><td>0.1</td><td>0</td></tr><tr><td>3</td><td>0.1</td><td>0</td></tr></table></td><td>See table 6</td><td>PASS</td></tr>
<tr><td>7.1.2.2.2 Transmittance – Oculars with filtering action
(EN 167: 2001 Clause 6≠)</td><td>The transmittance of oculars with filtering action shall meet the requirements given in the specific standards relating to the various types of oculars.</td><td><table><tr><th>Sample</th><th>Luminous transmittance %</th></tr><tr><td>4L</td><td>87.4</td></tr><tr><td>4R</td><td>87.5</td></tr><tr><td>5L</td><td>87.7</td></tr><tr><td>5R</td><td>87.9</td></tr><tr><td>6L</td><td>87.6</td></tr><tr><td>6R</td><td>87.9</td></tr></table></td><td>± 0.72 %</td><td>PASS</td></tr>
<tr><td>7.1.2.3 Diffusion of light
(EN 167: 2001 Clause 4≠)</td><td>Maximum value of reduced luminance factor shall be:
1.00 $\frac{cd}{m^2 \cdot lx}$ for welding filters;
0.75 $\frac{cd}{m^2 \cdot lx}$ for oculars used in eye-protector against high speed particles;
0.50 $\frac{cd}{m^2 \cdot lx}$ for all other oculars</td><td><table><tr><th>Sample</th><th>Reduced luminance factor / $cd.m^{-2}lx^{-1}$</th></tr><tr><td>4R</td><td>0.39</td></tr><tr><td>4L</td><td>0.49</td></tr><tr><td>5R</td><td>0.43</td></tr><tr><td>5L</td><td>0.46</td></tr><tr><td>6R</td><td>0.39</td></tr><tr><td>6L</td><td>0.46</td></tr></table></td><td>± 17 %</td><td>PASS</td></tr>
</table>

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Clause / Test	Requirement	Test Results		UoM (See note D)	Result
7.1.3 Quality of material and surface (EN 167: 2001 Clause 5≠)	Except for a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring grains, pocking, scaling and undulation	Specimen	Defects	N/A	PASS
		1	A few minor scratches on sample one, but not considered significant		
		2			
		3			
7.1.4.2.2 Increased robustness – Complete eye-protectors and frames (EN 168: 2001 Clause 3.2)	On testing, the following defects shall not occur: • ocular fracture; • ocular deformation; • ocular housing or frame failure; • lateral protection failure	**Temperature**	**+55°C**	N/A	See Note B
		Left centre	OD		
		Right centre	OD		
		Left centre	OD		
		Right centre	OD		
		Left lateral	OD		
		Right lateral	OD		
		Temperature	**-5°C**		
		Left centre	OD		
		Right centre	OD		
		Left centre	OD		
		Right centre	OD		
		Left lateral	OD		
		Right lateral	OD		
7.1.5.1 Stability at an elevated temperature (EN 168: 2001 Clause 5)	Assembled eye-protectors shall show no apparent deformation	No deformation was observed		N/A	PASS
7.1.7 Resistance to ignition (EN 168: 2001 Clause 7)	No part of the eye-protector shall ignite or continue to glow after removal of the steel rod	No part of any sample ignited or exhibited any after-glow after contact with the heated rod		N/A	PASS
7.2.4 Protection against droplets and splashes of liquids	Face-shields shall cover the eye region rectangle ABCD Face shields shall have a viewing area with a minimum centre-line depth of 150 mm	Specimen	Covers rectangle ABCD	N/A	PASS
		1	Yes		
		2	Yes		
		3	Yes		
		Specimen	Centre-line depth		
		1	178 mm		
		2	180 mm		
		3	180mm		

APPENDIX 06

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Additional Information / Notes

Table 6 – Additional uncertainty of measurement information

Clause	Test / Component	UoM (see note D)
EN 167:2001 3 Spherical, astigmatic and prismatic refractive powers	Spherical and astigmatic powers	± 0.01 m^{-1}
	Prismatic difference	± 0.08 cm/m

Note D – 'UoM' denotes estimated Uncertainty of Measurement for stated test results. This uncertainty value is based on a standard uncertainty multiplied by a coverage factor k = 2, which provides for a confidence level of approximately 95%

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TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.

1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.

1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing

1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.

1.5 All references in these terms and conditions to:

(a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
(b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
(c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).

1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.

1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.

2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.

2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.

2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.

2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.

2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.

2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.

2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.

2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.

2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.

3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.

3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.

3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.

3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.

3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.

5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:

(a) death or personal injury caused by its negligence or the negligence of its employees or agents;
(b) fraud or fraudulent misrepresentation;
(c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
(d) defective products under the Consumer Protection Act 1987; or
(e) any other liability which cannot be limited or excluded by applicable law.

5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.

5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.

6.3 The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.

6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.

6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.

7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.

7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.

7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.

7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.

9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.

9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

SATRA TECHNOLOGY

TECHNICAL REPORT

UKAS TESTING
0248

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

10. PROVISION OF SERVICES

10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.

10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.

10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12. DELIVERY AND NON-DELIVERY OF GOODS

12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13. RISK/TITLE OF GOODS

13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

13.2 The Company shall not accept responsibility for loss or damage in transit unless:

a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and

b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

13.4 Until ownership of Goods has passed to the Client, the Client shall:

a) hold the Goods as SATRA's bailee;

b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);

c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and

d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and

b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and

c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14. PATENTS

14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15. WARRANTY OF GOODS

15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16. DEFECTIVE GOODS

16.1 Subject to clauses 16.6 and 16.7 if:

a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and

b) SATRA is given a reasonable opportunity of examining such Goods; and

c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or

b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or

c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or

d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;

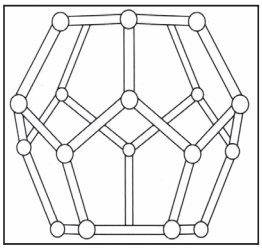
b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – September 2019

Signed:

Zotefoams plc



Technical Information Sheet TIS 25
(previously BTI18)
Compliance of Azote Foams with Standards for Medical Appliances

INTRODUCTION

Zotefoams foam products are widely used in medical appliances and packaging applications, where the product purity and stability is greatly valued.

Medical appliances have to comply with strict regulations as described in EU Directive 93/42/EC. This directive describes the requirements for medical devices and thereby also covers the requirements of the component materials used in the manufacture of such devices.

The evaluation of medical devices / materials is comprehensively covered by the International Standard, ISO 10993 which to date is split into 18 separate parts. This set of standards outlines tests methods and requirements for various situations, covering the levels and types of contact of a device (and the materials it is made from) with the body (and bodily fluids).

A further set of recognised tests for polymers and plastics are those described under US Pharmacopoeia Monograph <661> or USP<661>. The USP tests are designed to characterize the physical and chemical properties of plastics by means of four specific tests; non-volatile residue, residue on ignition, buffering capacity and heavy metals content (Pb, Hg, Cr^{6+}, Cd).

The assessments that follow were based on the full testing of a selected foam sample (Plastazote® LD45 Pink) with subsequent demonstration of the toxicological equivalence of the other foams to this representative sample in accordance with the ISO 10993 standard.

SCOPE OF THE EVALUATION

A wide range of Zotefoams products have been assessed for their suitability as parts of surface devices in contact with skin and surface devices in contact with mucosal membranes or breached or compromised surfaces for limited or prolonged exposure (single, multiple or long term use or contact up to 30 days) either directly or through showing toxicological equivalence in accordance with ISO 10993.

The relevant sections in ISO 10993: Biological Evaluation of Medical Devices, are:

ISO 10993: Part 1 [Evaluation and Testing] provides guidance on the types of tests required for a certain level of contact between the device and body. It expresses the fundamental principles of toxicity evaluation which are then subdivided under several headings.

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ISO 10993: Part 5 [Tests for In-vitro Cytotoxicity] describes the test methods used to assess in-vitro cytotoxicity of medical devices and component materials. These tests cover exposure of cell cultures either to the device or to extracts from the device. After a controlled incubation period the test cells are visually assessed for changes with quantification of the effect of exposure on cell growth. Dependent on this evaluation the sample is then classed as non-cytotoxic, mildly cytotoxic, moderately cytotoxic or severely cytotoxic.

ISO 10993: Part 10 [Tests for Irritation and Delayed-type Hypersensitivity] outlines the test methods used to assess the potential for irritation and sensitisation during repeated and/or long term exposure to the device / material. A four tier approach is suggested for the assessment of the potential that the devices and / or materials have for causing irritation and sensitisation.

The primary skin irritation test used in these tests involved samples applied to the skin of a test animal (guinea pig). The sensitisation test animals are repeatedly exposed to the sample for several hours. The induction period is followed by 2 weeks without exposure to the samples after which a challenge exposure is applied. The reaction to this challenge is monitored and assessed after specific time intervals.

Results of these tests are based on the mean score of all test animals and responses are classed as negligible, slight, moderate or severe.

ISO 10993: Part 18 [Chemical Characterization of Materials] describes methods for the chemical characterisation of materials. This characterisation includes identification of the chemical nature of the sample and any additives or contaminants that are present. Chemical characterisation is usually performed on extracts of the sample since potential leachables are generally the cause of adverse reactions.

The information obtained from this characterisation can then be used to either identify harmful substances in the product or to establish toxicological equivalence between a known material / product and the test sample.

TEST PROGRAMME

Assessment of the suitability of the foam materials for use in medical devices was carried out by Rapra Technology Ltd, Shropshire, UK.

All foam samples in the table were initially tested according to the requirements of US Pharmacopoeia Monograph testing (USP <661>).

One foam grade, Plastazote® LD45 Pink, was then subjected to full biocompatibility testing as described above and in accordance with ISO 10993: Parts 1, 5, 10 and 18. Additionally other foam grades, selected with the highest density of each product range in Black or Silver Grey, were evaluated against ISO 10993: Part 18.

The information gained on this latter set of samples was used to establish toxicological equivalence between these foams and the fully tested Plastazote® LD45 Pink. Toxicological equivalence was established by comparison of US Pharmacopoeia Monograph testing (USP <661>) results and comparison of substances identified in

aqueous and isopropanol extracts of the samples, in accordance with ISO 10993: Part 18.

RESULTS SUMMARY & CONCLUSIONS

The study, completed in December 2005, concluded that:

'**all of the foam materials represent an acceptable risk for use in parts of surface devices in contact with skin and surface devices in contact with mucosal membranes or breached or compromised surfaces for limited or prolonged exposure (single, multiple or long term use or contact up to 30 days)**.'

This conclusion is a risk assessment based upon the levels of substances with known or suspected health risks, found in the aqueous and isopropanol extracts from the different foam grades.

The following table indicates the equivalence of the other foam samples tested (in terms of useable area x 1cm thick strip), in contact with the body and based upon changes either daily for 30 days or alternatively once after a full 30 day exposure.

PRODUCT	Maximum acceptable area of 1 cm thick foam [cm^2]	
	Daily changes of foam[1]	Change of foam after 30 days[2]
Plastazote® LD45 Pink[3]	n/a	n/a
Plastazote® LD70 Black	29000	870000
Plastazote® PK80 Silver Grey	10000	300000
Plastazote® HD115 Black	1900	57000
Evazote® EV50 Black	4600	140000
Evazote® VA80 Black	3400	100000
Supazote® EM45 Black	9100	270000

[1] *Assumes all leachable material is released to the patient in one day.*
[2] *Assumes all leachable material is released to the patient during the 30 day period of contact.*
[3] *Plastazote® LD45 Pink was the reference sample (full biocompatibility testing).*

Based on the establishment of toxicological equivalence, all foam grades mentioned in the table above which are of the same formulation but are either of lower density and / or in the colours Black, Grey, White or Pink are also considered to pose an acceptable risk for use in skin contact devices.

All foam samples in the table were tested and shown to comply fully with the requirements of US Pharmacopoeia Monograph <661>.

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PAST TESTING AND RESULTS

Prior to the general study above, foam samples from several grades have been tested in isolation to ISO 10993: Part 5 [Tests for In-vitro Cytotoxicity]. These tests were performed in various laboratories using various different types of cell cultures. In some cases the sample was tested using direct exposure while other cases involved tests of extracts of the sample.

In these past tests, the following materials were tested and found to be non-cytotoxic:

- Plastazote®
  - LD24 White, MP45 White
  - LD45 Pink, LD45 White
  - HD115 Black, HD115 White
- Evazote®
  - EV50 White, VA35 White
- Supazote® EM26 White

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ISO 14001
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