EU DECLARATION OF CONFORMITY

Manufacturer	Guilin HBM Health Protections Inc. No. 1-2, Shuijing East Road Economic & Technological Development Area 541805 Guilin, Guangxi, China
Manufacturer SRN	CN-MF-000033439
European Authorized Representative	HBM Medical Coliemore House, Coliemore Road Dalkey, Co Dublin A96 A8D5 Ireland
European Authorized Representative SRN	IE-AR-000031279
Product description	surgical and protective, latex powder-free gloves, sterile, for single use
Brand name	dermagel plus orthopedic
Reference numbers	RC100630 55-90_2937
Product code	MLOG55/60/65/70/75/80/85/90
Sizes	5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0
Basic UDI-DI code	697178707SGNRUF
EMDN Code	T01010102
Intended use	Sterile, surgical and protective gloves intended to be worn on hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment during surgical procedure. Chemo-risk gloves designed for protection while working with the administration of chemotherapy drugs. Gloves also intended to protect against radioactive contamination contact. Single use.
MDR classification	class IIa, Rule 6 according to Annex VIII of Regulation (EU) 2017/745
Conformity assessment procedure (MDR)	Annex IX, Chapter I and III
Notified Body (MDR)	BSI Group The Netherlands B.V., Notified Body No 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
CE Certificate number (MDR)	MDR 747912 R000
PPER classification	category III
Conformity assessment procedure (PPER)	EU Type-examination (Module B), Annex V & Module D, Annex VIII
EU Type-examination certificate notified body (PPER)	Satra Technology Europe Ltd, Notified Body No 2777 Bracetown Business Park, Clonee, Dublin 15 Dublin, Ireland
EU Type-examination certificate number (PPER)	2777/18178-04/E00-00

We, HBM Guilin Health Protections Inc., herewith declare under our own responsibility that above mentioned product:

1. is in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

Digitally signed by Iurcu Nicolae
Date: 2026.02.20 18:12:29 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

2. is in conformity with Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC;
3. is the subject to the EU Type certificate (Module B) number 2777/18178-04/E00-00, issued by notified body Satra Technology Europe Ltd, No 2777, Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland;
4. is the subject to the conformity assessment procedure to type based on conformity to type based on quality assurance of the production process (Module D) under surveillance of the notified body Satra Technology Europe Ltd, No 2777, Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland;

Applicable standards:

No	Standard	No	Standard
1	EN ISO 13485:2016	22	EN ISO 21420:2020
2	EN 455-1:2020+A2:2024	23	EN ISO 374-1:2016 + A1:2018
3	EN 455-2:2024	24	EN ISO 374-2:2019
4	EN 455-3:2023	25	EN ISO 374-4:2019
5	EN 455-4:2009	26	EN ISO 374- 5:2016
6	EN ISO 14971:2019+A11:2021	27	EN 16523-1:2015+A1:2018
7	EN ISO 15223-1:2021	28	EN 421:2010
8	EN ISO 20417:2021		
9	ISO 2859-1:1999+A1:2011		
10	EN ISO 10993-1:2020		
11	EN ISO 10993-5:2009		
12	EN ISO 10993-10:2023		
13	EN ISO 10993-11:2018		
14	EN ISO 10993-23:2021		
15	EN 556-1:2024		
16	EN ISO 11737-1:2018/A1:2021		
17	EN ISO 11737-2:2020		
18	EN ISO 11137-1:2015/A2:2019		
19	EN ISO 11137-2:2015/A1:2023		
20	EN ISO 11607-1:2020/A1:2023		
21	EN ISO 11607-2:2020/A1:2023		

Signed on behalf of the manufacturer:

Place, Date of issue: Guilin, Jan.03/2025

Signature:

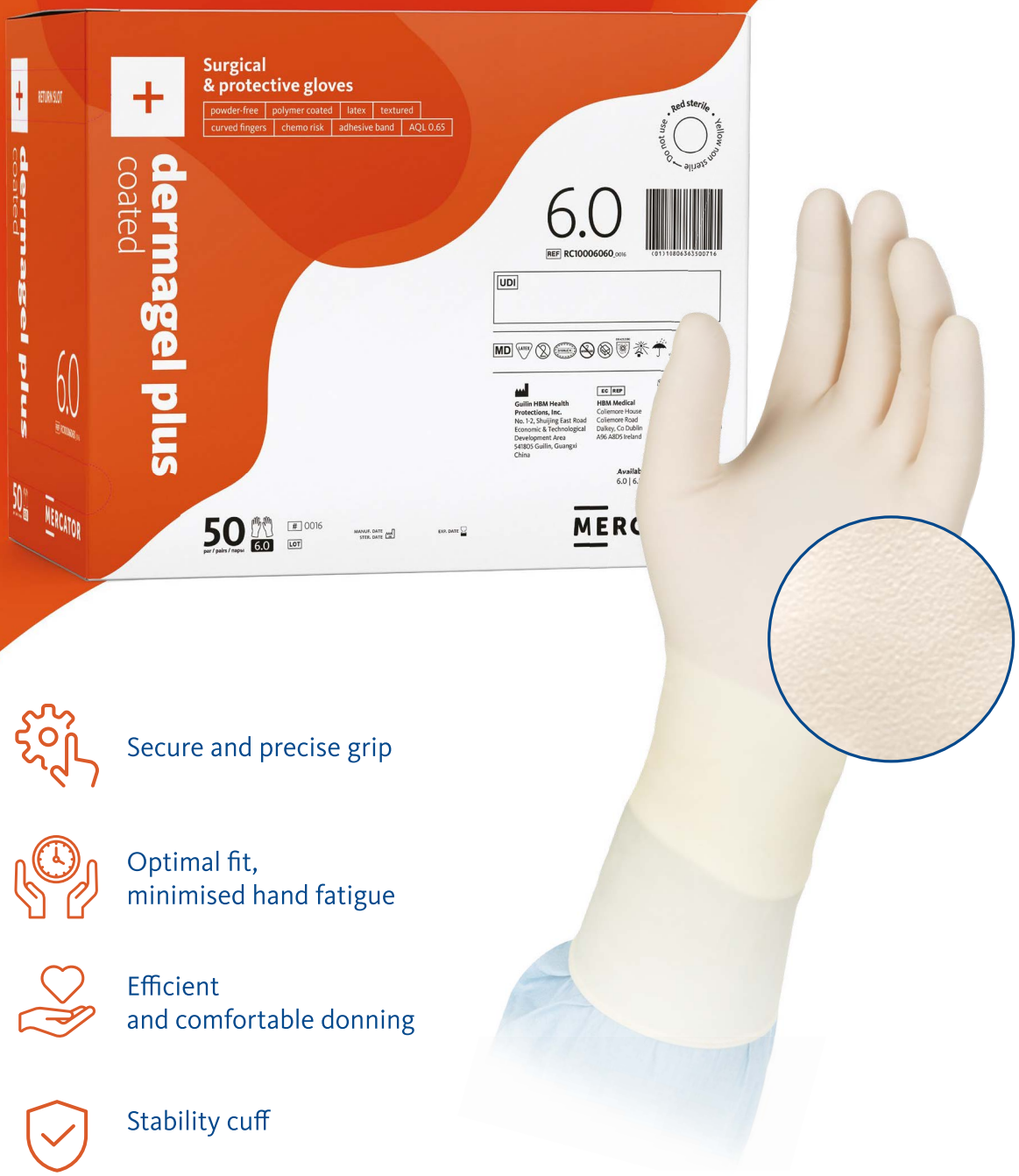
Name and position: Pu lei / Quality director

GUILIN HBM HEALTH PROTECTIONS, INC.

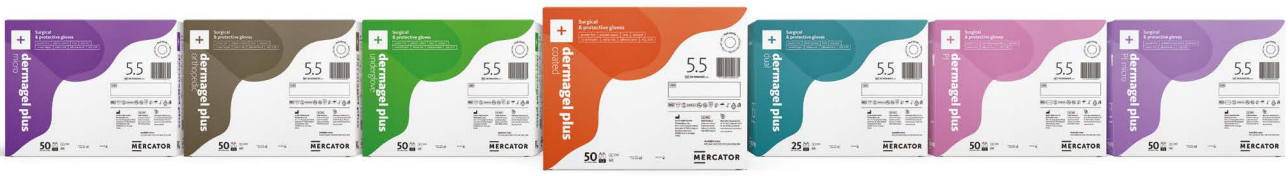
MERCATOR

dermagel plus

Higher safety standard

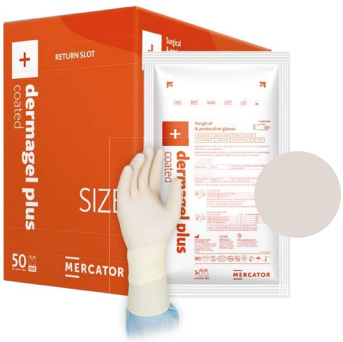


- Secure and precise grip
- Optimal fit, minimised hand fatigue
- Efficient and comfortable donning
- Stability cuff



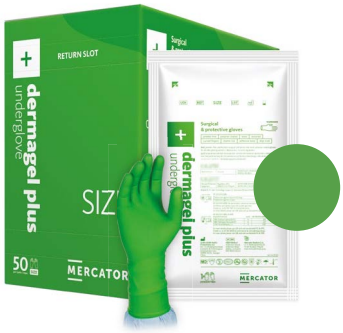
MERCATOR

+ dermagel plus



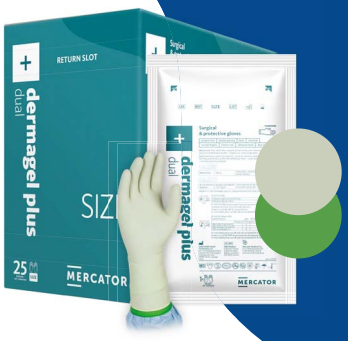
dermagel plus coated

Universal application



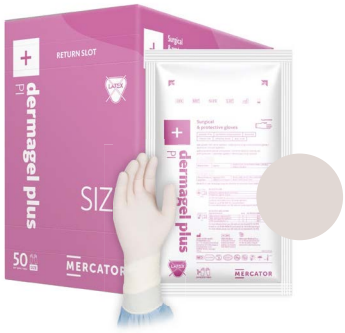
dermagel plus underglove

Inner glove in the **double gloving system**



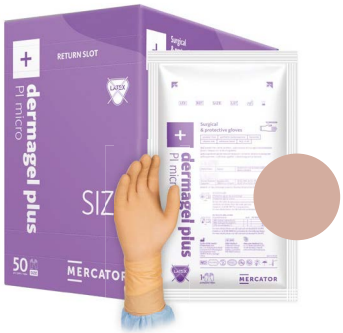
dermagel plus dual

Ready-to-use system for **easy identification of perforations**



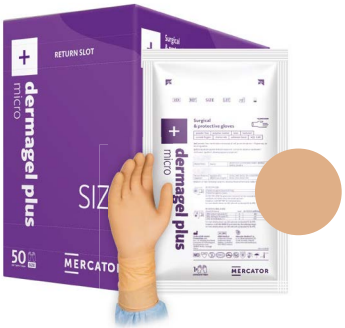
dermagel plus PI

Universal use, **for people prone to allergies**



dermagel plus PI micro

Increased **tactile sensitivity, for people prone to allergies**



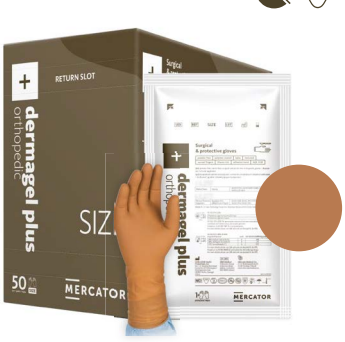
dermagel plus micro

Microsurgical procedures requiring increased **tactile sensitivity**

Features of the **dermagel plus** glove line

Length	min. 300 mm
Shape	anatomical
Sterilization method	STERILE R
Outer surface	textured
Inner surface	polymer coated
Cuff	beaded with adhesive band
AQL	0.65
CE classification	Medical device class IIa, Personal Protective Equipment (PPE) category III
Packaging	1 pair / dispenser 50 pairs / carton box 400 pairs
Available sizes	5.5* - 9.0

*size available on request



dermagel plus orthopedic

Orthopedic procedures requiring **enhanced protection against perforation**

This material is not a public advertisement within the meaning of the Medical Devices Act of 7 April 2022, and we request you not to disseminate it.

TECHNICAL DATA SHEET

dermagel plus orthopedic

PRODUCT DESCRIPTION

Type of the glove	Sterile powder-free surgical and protective gloves for single use
Intended use	Sterile, surgical and protective gloves intended to be worn on hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment during surgical procedure. Chemo-risk gloves designed for protection while working with the administration of chemotherapy drugs. Gloves also intended to protect against radioactive contamination contact. Single use.
Material	Natural rubber latex
Donning powder	None
Colour	Brown
Shape	Anatomic, curved fingers, hand specific
Cuff	Beaded, with adhesive band R/L and size marking at cuff
External surface	Textured (textured calibrated finger and inner side of the hand), polymer coated
Internal surface	Polymer coated
Packaging	1 pair per pouch, 50 pairs per dispenser, 400 pairs per carton

PHYSICAL PROPERTIES

Size		5.5*	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Length [mm]	EN 455-2 normative value	250	260	260	270	270	270	280	280
	Spec. [min]	300	300	300	300	300	300	300	300
Width [mm]	EN 455-2 normative value	72 ±4	77 ±5	83 ±5	89 ±5	95 ±5	102 ±6	108 ±6	114 ±6
Thickness single wall [mm]	Middle finger [min]	0,30							
	Palm [min]	0,28							
	Cuff [min]	0,22							
Force at break [N] Minimum	Before aging EN 455-2 normative value	9,0							
	After aging EN 455-2 normative value	9,0							
Ultimate Elongation[%] Minimum	Before aging ASTM D 3577 normative value	750							
	After aging ASTM D 3577 normative value	560							
Powder content [mg/glove]	EN 455-3 normative value	<2							
Latex protein content [µg/g glove]	EN 455-3 modified Lowry's assay	<50							

MANUFACTURING AND SAFETY STANDARDS

Manufacturer	Guilin HBM Health Protections Inc. No. 1-2, Shuijing East Road Economic & Technological Development Area 541805 Guilin, Guangxi, China	
Authorized Representative	HBM Medical Coliemore House, Coliemore Road Dalkey, Co Dublin A96 A8D5 Ireland	
Importer	Mercator Medical S.A. H. Modrzejewskiej 30 Street 31-327 Cracow, Poland	
AQL	Manufacturing final release: G-I inspection level AQL 0.65 in accordance with ISO 2859-1.	
Sterilization	Irradiation / E-beam (R)	
Classification	**Medical Device:** class IIa Rule classification acc. to declaration of conformity	**Personal Protective Equipment:** Category III (Regulation (EU) 2016/425) Type B (EN ISO 374-1)
Conformity assessment body	BSI Group The Netherland B.V., Notified Body No 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands	Satra Technology Europe Ltd, Notified Body No 2777 Bracetown Business Park, Clonee, Dublin 15 Dublin, Ireland
Product compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 2859-1, EN ISO 15223-1, EN ISO 20417, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-11, EN ISO 10993-23, EN 556-1, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11137-1, EN ISO 11137-2, EN ISO 11607-1, EN ISO 11607-2	EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1, EN ISO 21420, EN 421 (Radioactive contamination only)
Quality management standards	EN ISO 13485, ISO 9001, ISO 14001	

桂林恒保健康防護有限公司
GUILIN HBM HEALTH PROTECTIONS, INC.
地址：桂林市桂林经济技术开发区水荆东路1-2号
ADD: No.1-2, Shuijing East Road, Economic and Technological Development Area, Guilin, China
TEL：0773-8569066 / 0773-8569067 E-mail: guilinhbm@hbmchina.com
www.hbmchina.com

Viral test penetration	Test in accordance with EN ISO 374-5 (ISO 16604) and ASTM F1671.
Bacteria and fungi penetration	Test in accordance with EN ISO 374-5 (EN ISO 374-2).
Synthetic blood penetration	Test in accordance with ASTM F1670.
Chemotherapy drugs permeation test	Test in accordance with ASTM D6978.
Chemical substances permeation test	Test in accordance with EN 16523-1.
Radioactive contamination protection test	Test in accordance with EN 421 – protection against radioactive contamination only.
Biocompatibility/ biological evaluation	Test in accordance with EN ISO 10993-5. No cytotoxic evidence observed. Test in accordance with EN ISO 10993-10. No skin irritation and sensitization evidence observed. Test in accordance with EN ISO 10993-11.
Production technology	Chlorine-free production process.
REACH	The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.

STORAGE AND DISPOSAL

Long-term storage instructions	It is recommended to store the gloves in dry place, in the temperature of 5-40°C and to protect them against direct sunlight. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.
Transport instructions	Transport in conditions ensuring an appropriate hygienic standard, protecting the product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis).
Shelf life	3 years from manufacturing date
Product disposal	Used product should be treated as contaminated material, therefore local regulations regarding the disposal of such materials should be applied.
Packaging disposal	Master packaging (carton, dispenser) is made of homogeneous material, does not contain any foil elements, does not contain any different type of materials, does not need to be separated into fractions. Packaging is 100% recyclable, in accordance with local regulations. Unit packaging (outer envelope and inner envelope) is to be regarded as contaminated medical material and local regulations for the handling of such materials must be followed.

PRODUCT REFERENCES

Size / REF number

5.5*	6.0	6.5	7.0	7.5	8.0	8.5	9.0
RC10063055_2937	RC10063060_2937	RC10063065_2937	RC10063070_2937	RC10063075_2937	RC10063080_2937	RC10063085_2937	RC10063090_2937

* size available on request

Date: 16.12.2024, Rev. 1.0

2937

Issued to:

Guilin HBM Health Protections, Inc.
No.1-2 Shuijing East Road
Economic Development Zone
Guilin City
China

Notified Body: 2777

SATRA customer number: P20293

EU Type-Examination Certificate

Certificate number: 2777/18178-04/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference:
HBM Surgical Gloves

Description:
HBM, Latex powder free surgical gloves

Cream Latex Surgical Glove Sizes MTPC55 through to MTPC90
Green Latex Surgical Glove Sizes MLUG55 through to MLUG90
Cream Latex Surgical Glove Sizes MLSG55 through to MLSG90
Brown Latex Surgical Glove Sizes MLOG55 through to MLOG90
Cream/transparent Latex Surgical Glove Sizes MPND55 through to MPND90

Sizes:
5.5
6.0
6.5
7.0
7.5
8.0
8.5
9.0

Classification:

EN ISO 374-1: 2016+ A1 2018/Type B	Level	EN ISO 374-4: 2019 Degradation %
Sodium hydroxide 40% (K)	6	-6.0
Hydrogen peroxide 30% (P)	6	-2.1
Formaldehyde 37% (T)	6	-19.1

EN ISO 374-5: 2016	Result
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

EN 421:2010
Radioactive contamination only

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016; EN 421:2010 (Radioactive contamination only)

Technical reports/Approval documents:
SATRA: CHM0301662/2034/LH/C, CHM0301661/2034/LH/A/Final, CHM0301662/2034/SPT, CHM0301662/2034/LH/A/Final, CHM0301662/2034/LH/B/Final, SPC0309209/2111/Issue 2,CHM1879Q1Z1 2334 1

Signed on behalf of SATRA: Kayleigh Aylward

Kayleigh Aylward

Date first issued: 25/08/2021
Date of issue: 18/09/2024
Expiry date: 18/09/2029

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU or UKCA declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11).
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification, or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials, or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.