MERCATOR MEDICAL

EU DECLARATION OF CONFORMITY

Manufacturer: **MERCATOR MEDICAL S.A.**
UL. H.MODRZEJEWSKIEJ 30
31-327 KRAKÓW, POLSKA

Declares under its sole responsibility that non-sterile examination and protective gloves:

Brand	Type	Sizes	Batch numbers
dermagel® coated	latex, powder free, inner polymer coated, for single use	XS (5-6) - XL (9-10)	a'100 RD10006001-05
Basic UDI-DI: 5906615 RD NS L PF 92			

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, are classified as medical device class I according to Annex VIII of the Regulation (EU) 2017/745 and comply with European harmonized standards: EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006, EN 455-4:2009, EN ISO 15223-1:2016, EN 1041:2008.

The products described above are also classified as Personal Protective Equipment Category III and comply with Regulation (EU) 2016/425 of the European Parliament and the Council of 9 March 2016 on Personal Protective Equipment and resolution of the Council Directive 89/686/EEC and European standards: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016.

The products described above are identical to the Personal Protective Equipment, which is the subject to the EU Type Examination (Module B) under certificate No. 2777/12705-01/E01-01 issued by notified body:

Satra Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

Satra Technology Europe Limited (2777)
Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Date and place of issue:
05.05.2020, Kraków

MERCATOR MEDICAL S.A.
ul. Heleny Modrzejewskiej 30, 31-327 Kraków
tel. 12 66 55 400, fax 12 66 55 415
Rejestracja: Sąd Rejonowy dla Krakowa - Śródmieścia w Krakowie,
XI Wydział Gospodarczy KRS, KRS: 0000036244
Kapitał zakładowy (w całości wpłacony): 10.589.100 PLN
NIP: 677-10-36-424, REGON: 350967107
Numer BDO: 000056063

Signed on the behalf of the Manufacturer:

Wojciech Hercka
Product Documentation Manager

Issued to:

Mercator Medical S.A.
Ul. H. Modrzejewskiej 30
31-327 Krakow
Poland

Notified Body: 2777

SATRA customer number: P19011

EU Type-Examination Certificate

Certificate number: 2777/12705-01/E01-01

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:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

Dermagel coated

Description:

Five finger cream coloured Latex powder free examination gloves

Sizes:
5-6 – XS
6-7 – S
7-8 – M
8-9 – L
9-10 – XL

Classification:

EN ISO 374-1:2016 Type B	Level	EN 374-4:2013
40% Sodium hydroxide (K)	4	-59.2%
30% Hydrogen peroxide (P)	2	4.3%
37% Formaldehyde (T)	5	-23.6%
1.5% Methanol	6	6.1%
10% Acetic acid	1	-1.4%
50% Benzalkonium chloride	2	-10.7%
4% Chlorhexidine digluconate	6	-13.1%
10% Phosphoric acid	6	-18.4%
12% Sodium hypochlorite	6	-25.4%
50% Sulphuric acid	6	-22.1%
5% Ethidium bromide	6	-24.7%
3% Hydrogen peroxide	6	-2.6%
5% Glutaraldehyde	6	-8.9%
0.1% Phenol	6	-32.7%

EN ISO 374-5:2016
Protection against bacteria and fungi – Pass
Protection against Viruses – Pass

Standards/Technical specifications applied:
EN ISO 374-1:2016; EN ISO 374-5:2016; EN 420: 2003+A1: 2009

Technical reports/Approval documents:
SATRA: CHM0276315/1840/LH/P, CHM0276315/1840/LH/H, CHM0276315/1840/LH/D, CHM0276315/1840/2/SPT, CHM0276315/1840/LH/G, CHM0276315/1840/LH/F, CHM0276315/1840/LH/E, CHM0276315/1840/LH/R

Signed on behalf of SATRA: Geoff Graham Jacque Glasspool

Date of issue: **21/08/2019** **Expiry date:** **15/05/2024**

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.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (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 manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
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 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 Regulation 2016/425.