

**EU DECLARATION OF CONFORMITY**

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

SRN: PL-MF-000018942

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

Brand	Type	Sizes	Reference numbers
<b>dermagel® coated</b>	latex, powder free, inner polymer coated, for single use	XS (5-6) - XL (9-10)	a'100: RD10006001-05
<b>Basic UDI-DI: 5906615 RD NS L PF 92</b>			
<b>Intended use: non-sterile examination and protective gloves, for single use</b>			

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, rule 5, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

The products described above are 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 ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

The products described above are 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

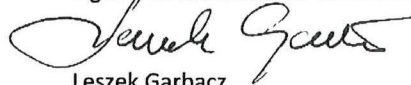
and are subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body:

**Satra Technology Europe Limited (2777)**

Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Date and place of issue:  
23.02.2022, Kraków

Signed on the behalf of the Manufacturer:



Leszek Garbacz  
Product Documentation Manager

MERCATORMEDICAL

**EU IZJAVA O SKLADNOSTI**

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

SRN: PL-MF-000018942

Izjavlja na izključno svojo odgovornost, da so ne sterilne medicinske in zaščitne rokavice:

Znamka	Tip	Velikosti	Kataloške številke
dermagel® coated	Lateks, brez pudra, notranjost prevlečena s polimerom, za enkratno uporabo	XS (5-6) - XL (9-10)	a'100: RD10006001-05
<b>Basic UDI-DI: 5906615 RD NS L PF 92</b>			
Namen uporabe: pregledne in zaščitne nesterilne rokavice, za enkratno uporabo			

v skladu z določbami Uredbe o medicinskih pripomočkih (EU) 2017/745 Evropskega parlamenta in Sveta z dne 5. aprila 2017 o medicinskih pripomočkih, so razvrščeni kot medicinski pripomoček razreda I v skladu s prilogo VIII Uredbe (EU) 2017/745 in ustrezajo harmoniziranim standardom: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

Izdelki so prav tako klasificirani kot osebna varovalna oprema, razvrščeni v kategorijo III in so v skladu z določbami Uredbe (EU) 2016/425 Evropskega parlamenta in Sveta z dne 9. marca 2016 o osebni varovalni opremi in razveljavitvi Direktive Sveta 89/686/EGS ter ustrezajo harmoniziranim standardom: EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

Izdelki ustrezajo osebni varovalni opremi, ki so predmet ugotavljanja skladnosti po EU – pregleda tipa (modul B) z izdanim certifikatom št. 2777/12705-01/E01-01 s strani priglašene organa:

**Satra Technology Europe Limited (2777)**

Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Izdelki so skladni s tipom, ki temelji na notranji kontroli proizvodnje plus nadzorovanih preskusov proizvodov v naključno izbranih časovnih presledkih (modul C2) pod nadzorom priglašene organa:

**Satra Technology Europe Limited (2777)**

Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Datum in kraj izdaje:

23.02.2022, Krakow

Podpisano v imenu proizvajalca:

Leszek Garbacz

Vodja dokumentacije izdelkov