MERCATOR

Translation from Polish

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	Packaging	Sizes	Reference Numbers
nitrylex basic	nitrile, powder-free, for single use, blue	a'100	XS - XXL	RD30292001-06_3000
Basic UDI-DI: 5906615 RD NS N PF 9C				
Intended use: gloves intended for use in medical field to protect patient and user from cross-contamination, preventing perioperative infections during medical procedures (e.g. intravenous, intramuscular, intraarterial injections, dressing changes, wound revision, removal of surgical sutures), conducting medical examinations and medical treatment procedures, conducting diagnostic and therapeutic procedures, for handling medical contaminated material, intended to be used on one individual during a single procedure				

meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices. The products described above are classified as medical device class I, rule 5, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards **(see Table 1).**

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 European standards **(see Table 1)**.

The products described above are subject to the EU type-examination (Module B) under EU type-examination certificate no. **(see Table 1)** issued by notified body **(see Table 1).**

Products are also subject to the conformity to type procedure based on the internal production control plus supervised product checks at random intervals (Module C2) or conformity to type procedure based on quality assurance of the production process (Module D), under surveillance of the notified body **(see Table 1).**

Table 1					
Reference numbers	**Compliance with European standards [MD]**	**Compliance with European standards [PPE]**	**EU type-examination Certificate number – Module B**	**Notified Body – Module B**	**Notified Body – Module C2/D**
RD30292001-06_3000	EN 455-1:2020+A2:2024 EN 455-2:2024 EN 455-3:2023 EN 455-4:2009 EN ISO 15223-1:2021 EN ISO 20417:2021	EN ISO 21420:2020 EN ISO 374-1:2016+A1:2018 EN ISO 374-2:2019 EN 16523-1:2015+A1:2018 EN ISO 374-4:2019 EN ISO 374-5:2016	2777/14815-05/E01-01	Module B: Satra Technology Europe Limited (2777)	Module D: Satra Technology Europe Limited (2777)

Date and place of issue:
17.12.2025, Kraków

Signed on the behalf of the Manufacturer:
[Signature]
Leszek Garbacz
Regulatory and Documentation Manager
PRRC