MERCATOR

Translation from Polish

EU DECLARATION OF CONFORMITY

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

SRN: PL-MF-000018942

Declares under its sole responsibility that:

Brand	Description	Colour	Reference Numbers
OPERO Mask 3-ply non-woven ECO face mask with earloops	3-ply non-woven face mask with earloops	white	W413300130_0028
		green	W413200130_0028
		blue	W413100130_0028
OPERO Mask 3-ply non-woven ECO face mask with ties	3-ply non-woven face mask with ties	white	W411300130_0028
		green	W411200130_0028
		blue	W411100130_0028
Basic UDI-DI: 5906615 W41 NS NW G YH			
EN 14683:2019+AC:2019	**Type II**		
Intended use: Medical device (medical mask type II) covering mouth and nose, constituting a barrier that minimizes direct transfer of infectious agents between staff and patient, and to limit transfer of microorganisms and bacteria to surgical wound, which limits the possibility of wound infection and reduces risk of postoperative complications, or generally reduces possibility of transmitting pathogenic microorganisms. For use during surgery and other medical settings with similar requirements. For use by qualified personnel (professional users). Single-use product, not sterile.			

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 1, according to Annex VIII of the Regulation (EU) 2017/745 and comply with European standards: EN 14683:2019+AC:2019, EN ISO 15223-1:2021; EN ISO 20417:2021

Date and place of issue:
03.03.2025, Kraków

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