

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 surgical mask type IIR with earloops	3-ply surgical mask type IIR with earloops	blue	W413110030_0028
Basic UDI-DI: 5906615 W41 NS NW G YH			
EN 14683:2019+AC:2019		Type II R	
Intended use: Medical device (surgical mask type IIR) covering mouth and nose, constituting a barrier that minimizes direct transfer of infectious agents between staff and the patient, and to limit the transfer of microorganisms and bacteria to the surgical wound during surgery, which limits possibility of wound infection and reduces the risk of postoperative complications. . For use during surgical procedures. For use by qualified personnel (professional users). Single-use product, non 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:
20.06.2024, Kraków

Signed on behalf of the Manufacturer:



Leszek Garbacz
Regulatory and Documentation Manager
PRRC