

EU DECLARATION OF CONFORMITY

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

SNR: PL-MF-000018942

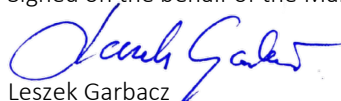
Declares under its sole responsibility that:

Brand	Description	Color	Reference Numbers
OPERO® 3-ply non-woven face mask with back ties	3-ply non-woven face mask with back ties	white	W411300030_0028
		green	W411200030_0028
		blue	W411100030_0028
Basic UDI-DI: 5906615 W41 NS NW T ZB			
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, 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 1041:2008+A1:2013.

Date and place of issue:
10.07.2024, Kraków

Signed on the behalf of the Manufacturer:



Leszek Garbacz
Product Documentation Manager
PRRC