

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: Masks protect against the spread of infectious agents. Non-sterile, for single use. | | | |

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:
04.11.2022, Kraków

Signed on the behalf of the Manufacturer:



Leszek Garbacz
Product Documentation Manager