FEARLESS PERFORMANCE®

# EU Declaration of Conformity

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|---|---|---|
| **Manufacturer:** | **Granberg AS**<br>Bjoavegen 1442, NO-5584 Bjoa, Norway | **E-mail**: post@granberg.no<br>**Phone**: +47 53 775 300 |
| **Single Registration number (SRN):** | NO-MF-000000207 | |

## REF. 210.0022E

The item is in conformity with (EU) 2017/745 Medical Device Regulation (MDR) as:

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|---|---|
| **Name** | Disposable Surgical Face Mask Granberg® |
| **Description** | Type IIR, non-sterile, blue |
| **Risk Classification** | Class I according to Rule 1 of Annex VIII of Regulation MDR (EU) 2017/745 |
| **Applied normative standards** | EN 14683:2019+AC:2019, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010EN ISO 14971:2019ISO 15223-1:2021, EN ISO 20417:2021 |
| **Intended Use** | Medical face masks are designed to prevent transmission of infected agents, blood and/or bodily fluids from the person wearing them (including healthcare personnel and patients) to others. |
| **Basic UDI-DI** | 702377GR210PPNSSM |
| **REF and available sizes** | REF. 210.0022E - one size |

The technical documentation for assessing the conformity of the medical devices with MDR has been developed in accordance with Annexes II and III of MDR.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer – Granberg AS.

Signed for Granberg AS:

Ole Marthon Granberg

Managing Director

Place and date of issue:

Bjoa, 06.12.2023