EU Declaration of Conformity

Manufacturer:	**Granberg AS** Bjoavegen 1442, NO-5584 Bjoa, Norway	**E-mail**: post@granberg.no **Phone**: +47 53 775 300
Single Registration number (SRN):	NO-MF-000000207	**Doc Nr: F/MD/016**

REF. 114.626

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

Name	Disposable Examination and Protective Nitrile Gloves Granberg®
Description	non-sterile, powder-free
Risk Classification	Class I according to Rule 1 and 5 of Annex VIII of Regulation MDR (EU) 2017/745
Applied normative standards	ISO 9001:2015, EN ISO 13485:2016, EN 455-1:2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, EN ISO 14971:2019+A11:2021, ISO 15223-1:2021, EN ISO 20417:2021
Intended Use	Powder-free examination and protective disposable nitrile gloves intended for use in the medical field to protect patients and users from cross-contamination. These gloves are also intended to protect against certain chemicals, microorganisms, and radioactive contamination, where hand protection is needed.
Basic UDI-DI	702377GR114NLNSSE
Available sizes	S - XL
EMDN Code	T01020204

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.

The product described above is also meeting requirements of **Category III** Personal Protective Equipment (PPE) and complies with the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment and European harmonized Standards EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 as **Type B**, EN ISO 374-5:2016 including **virus** protection and EN 421:2010 protection against radioactive contamination.

The product is identical to the PPE, which is the subject of the EU Type Examination (Module B) certificate of conformity no. **2777/10015-08/E07-01** issued by Notified Body:

Satra Technology Europe Limited, (NB No. 2777), Bracetown Business Park, Clonee, Dublin D15YN2P, Republic of Ireland.

Furthermore, the product is subject to the conformity to type, based on internal production control plus supervised product checks at random intervals (Module C2) of the Regulation 2016/425 under the surveillance of the Notified Body:

Satra Technology Europe Limited, (NB No. 2777), Bracetown Business Park, Clonee, Dublin D15YN2P, Republic of Ireland.

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, 06.02.2025