# EU DECLARATION OF CONFORMITY

The manufacturer declares on its sole responsibility that the product model

**NG-20**
**ProDon™ Nitrile Exam Gloves**
**Basic UDI-DI:** 709005815NG-20ZS
**EMDN:** T01020204 **GMDN:** 56286

meets the provisions in Regulation (EU) 2017/745 of April 5th 2017 on medical devices, classified as a class I medical device, and complies with European harmonized standards, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ISO 15223-1:2021 and EN ISO 14971:2019.

The product model meets the provisions in Regulation (EU) 2016/425 of March 9th 2016 on personal protective equipment, classified as a category III personal protective equipment and complies with EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019 and EN ISO 374-5:2016.

EU type-examination (module B) for the personal protective equipment has been conducted, and certificate no. 2777/14815-03/E28-01 was issued on May 22, 2021 by the following Notified Body;

**Satra Technology Europe Limited (2777)**
Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland

Petter Songe-Møller
Managing Director



**Manufacturer:** **TEGA GROUP AS** Energivegen 20, 4056 Tananger, NO
**Org no.** NO925676608
**SRN** NO-MF-000022607
**Phone** +47 51 29 01 41
**E-mail** compliance@tega.no