EU DECLARATION OF CONFORMITY

The manufacturer declares on its sole responsibility that the product model

NG-11
TEGA® Nitrile Exam Gloves
Basic UDI-DI: 709005815NG-11ZR
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

TEGA
FOR AND BEHALF OF
TEGA GROUP AS

Petter Songe-Møller
Managing Director

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