EU DECLARATION OF CONFORMITY

The manufacturer declares on its sole responsibility that the product model

NG-10

TEGA® Nitrile Exam Gloves

Basic UDI-DI: 709005815NG-10ZP **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

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Petter Songe-Møller Managing Director

TG-30879 V1 15.01.23

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