EU Declaration of Conformity

Product Brand:	TEGA®
Product Description:	TEGA Nitrile Exam Gloves
Product Model:	NG-11
Basic UDI-DI:	709005815NG-11ZR
Manufacturer:	TEGA GROUP AS Energivegen 20 4056 Tananger Norway
SRN:	NO-MF-000022607

Issue date:	22.12.2023
Valid to:	22.12.2025

TEGA GROUP AS hereby declares that the above-mentioned product complies with

- **Regulation (EU) 2017/745** 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**, **EN ISO 20417:2021**, **EN ISO 15223-1:2021**, **EN ISO 14971:2019**, **EN ISO 10993-1:2018**, **EN ISO 10993-10:2010**, **EN ISO 10993-11:2017** and **EN ISO 13485:2016**.
- **Regulation (EU) 2016/425** 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) and Quality Assurance of the production process (Module D) performed by the Notified Body,

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

Certificate No. 2777/14815-03/E28-01

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

Petter Songe-Møller
Managing Director

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