DECLARATION OF CONFORMITY EU - MD

MANUFACTURER: reflexx IN SAFE HANDS	**REFLEXX S.p.A.** Via Passeri 2 - 46019 Viadana (MN) Italy e-mail: info@reflexx.com sito web: www.reflexx.com
Unique manufacturer registration number:	**IT-MF-000021631**

The undersigned REFLEXX S.p.A. with registered office in Via Passeri 2-46019 Viadana (MN) Italy, Share Capital € 1,200,000 euro (i.v.) VAT 02085450209 R.E.A. 223166, on their own and sole responsibility, as a manufacturer of the subject devices

DECLARES

that the group of Medical Devices described below complies with the instructions of EU REGULATION 2017/745 (MDR) and complies with the general safety and performance requirements (Annex I) and with the applicable technical standards, reported in the technical file (EN 455 1,2,3 & 4).
The Technical File containing the relevant documentation is prepared in accordance with Annex II and is kept at the Manufacturer and made available to the Competent Authority. The Manufacturer has implemented and maintains a procedure for post-sales surveillance in accordance with Annex III.

Medical device (MD)*:*	**Family: DISPOSABLE EXAMINATION NON-SURGICAL GLOVES** **Sub-family** *: non-sterile nitrile gloves* **CND T01020204** ***Code****: reflexx NBio* *-art. NBio/XS - art. NBio/S - art. NBio/M - art. NBio/L - art. NBio/XL* **Progressive number Attributed to the DM:** mis. XS/2265756 S/2265758 M/2265764 L/2265768 XL/2265771
Basic UDI-DI:	*803289163GNPFEQ*
Classification:	**Class I not sterile -** Rule 5 of Annex VIII of MDR

The company has certified its Quality Management System in compliance with EN ISO 9001: 2015 and EN ISO 13485:2016 (Certificate No. 1427.2023 and No. 0580.2024, issued by IMQ on 28.05.2024).

Place, Date

Viadana, 15/11/2024

Signature Legal Representative

Gianni Isetti

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