# DECLARATION OF CONFORMITY UE - MD

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| MANUFACTURER: reflexx IN SAFE HANDS | **REFLEXX S.p.A.**<br>Via Passeri 2 - 46019 Viadana (MN) Italy<br>e-mail: info@reflexx.com<br>website: 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 (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.

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| **Medical device (MD)*:*** | **Family: DISPOSABLE EXAMINATION NON-SURGICAL GLOVES**<br>**Sub-family** *: non-sterile latex gloves* **CND T010201**<br>Progressive number Attributed to the DM: mis. S/2333378 - M/2333382 - L/2333385 - XL/2333387- XXL/2333388<br><br>*Code: reflexx 98HR art. R98/ S – art. R98/ M – art. R98/ L– art. R98/ XL– art. R98/ XXL* |
| Basic UDI-DI: | *803289163GLPFEE* |
| 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 (Certificate No. 5010014617 Rev.001 issued by TUV Sud on 09.06.2021).

Place, Date | Signature Legal Representative

Viadana, , 06/12/2022 | Gianni Isetti

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