


# DECLARATION OF CONFORMITY UE - MD

MANUFACTURER:  I N S A F E H A N D S	<b>REFLEXX S.p.A.</b> Via Passeri 2 - 46019 Viadana (MN) Italy e-mail: <a href="mailto:info@reflexx.com">info@reflexx.com</a> website: <a href="http://www.reflexx.com">www.reflexx.com</a>
Unique manufacturer registration number:	<i>Not yet available</i>

The undersigned REFLEXX S.p.A. with registered office in Via Passeri 2-46019 Viadana (MN) Italy, Share Capital € 480,000 (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.

<b>Medical device (MD):</b>	<b>Family: DISPOSABLE EXAMINATION NON-SURGICAL GLOVES</b> <b>Sub-family : powder-free latex gloves CND T010201</b> Progressive number Attributed to the DM: mis. XS/1636536 S/1636537 M/1636538 L/1636539 XL/1636540  <i>Code: reflexx Care L600 art. L600/XS - art. L600/S - art. L600/M - art. L600/L - art. L600/XL</i>
Basic UDI-DI:	803289163GLPFEE
Classification:	<b>Class I not sterile</b> - 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 issued by TUV Sud on 06.21.2018).

Place, Date

Signature Legal Representative

Viadana, 01/03/2021

Gianni Isetti

**REFLEXX S.p.A.**  
Via Passeri 2 - 46019 VIADANA (MN)  
P.I. e C.F. 02085450209  
Tel.: 0375/833164 - Fax: 0375/464504  
e-mail: [info@reflexx.com](mailto:info@reflexx.com)