


DECLARATION OF CONFORMITY EU -PPE

MANUFACTURER:  I N S A F E H A N D S	REFLEXX S.p.A. Via Passeri 2 - 46019 Viadana (MN) Italy e-mail: info@reflexx.com website: www.reflexx.com
---	--

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 products indicated comply with EU Regulation 2016/425 as PPE and comply with EN 420:2003+A1:2009, EN ISO 374-1:2016 and EN ISO 374-5:2016.

Personal protective equipment (PPE):	<i>Name : powder-free latex gloves Reflexx 98</i> <i>Code: REFLEXX 98 reflexx 98HR art. R98/S – art. R98/M – art. R98/L – art. R98/XL – art. R98/XXL</i>
Risk category according to Annex I:	Category: III
Conformity assessment path:	<i>Conformity to the type according to module B</i> Modulo B_ CIMAC n. 0465; <i>EU-type examination certificate N° G-115-03514-20-Rev.1 of 15/01/2021</i> <i>Conformity to type based on internal production control combined with officially controlled product tests carried out at random intervals (module C2)</i> Modulo C2_ CIMAC n. 0465;

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

Legal Signature representative

Viadana, 10/10/2024

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