


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
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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 nitrile gloves Reflexx NBio</i> <i>Code: reflexx NBio art. NBio/XS art. NBio/S – art. NBio/M – art. NBio/L– art. NBio/XL</i>
Risk category according to Annex I:	Category: III
Conformity assessment path:	<i>Conformity to the type according to module B</i> <i>Modulo B_ CIMAC n. 0465; EU-type examination certificate N° G-115-05401-22 del 13/07/2022</i> <i>Conformity to type based on internal production control combined with officially controlled product tests carried out at random intervals (module C2)</i> <i>Modulo C2_ CIMAC n. 0465</i>

The company has certified its Quality Management System in accordance 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, 15/11/2024

Gianni Isetti

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