


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 ISO 21420:2020+A1:2024, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016 and EN 421:2010 (radioactive contamination only).

Personal protective equipment (PPE):	<i>Name : powder-free nitrile gloves Reflexx N75</i> <i>Code : reflexx N75</i> <i>art. N75/XS – art. N75/S – art. N75/M – art. N75/L – art. N75/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_ SATRA N. 2777, Technology Europe Ltd. Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland. EU type-examination certificate N°2777/27129-01/E01-01 on 03/09/2025</i> <i>Conformity to type based on quality assurance of the production process (Module D)</i> <i>Modulo D_ SATRA n. 2777;</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, 05/09/2025

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