

ROMED HOLLAND Declaration of Conformity

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 31-297-282 101 Fax: 31-297-288316 E-mail: info@romed.nl Website : www.romed.nl
SRN	NL-MF-000003481	
Product	Romed Nitrile Examination Gloves Purple Powder Free Extra Safe ® Ref: NTP795/800/805/810/815	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT III	
UMDNS	11882	
GMDN	56286	
Basic UDI-DI	871720243MDIGLNPEN0001VP	

We, with sole responsibility in drawing up this Declaration of Conformity, declare that the above mentioned product meets the provisions of the following EC Council Directives, Regulations and Standards. All supporting documentation is retained under the premises of the manufacturer.

The Romed Nitrile Examination Gloves Purple Powder Free Extra Safe:

- is identical to the PPE Regulation 2016/425 which is the subject of EU Type Examination certificate of conformity No. 060/2018/0111 issued by Centexbel Gent, Technologiepart 70, 9052 Zwijanaarde, Belgium
- is subject to the procedure set out in Module D of PPE Regulation 2016/425 under the supervision of the notified body SGS Fimko OY, P.O. Box 30 (Sarkiniementie 3), 00211 Helsinki, Finland.
- Certificate : MY18/1102977932

Product lot number: Assigning of lot number using 6 digits system as below:

YEAR		MONTH		RANDOM	

General applicable directives and regulations

REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
REGULATION (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Applicable standards

EN 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021 (cor. 2021-12).

No EU common specifications are applicable.

Wilnis, The Netherlands, 03 November 2022

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen

Managing Director

ISO 13485 MDD 93/42/EEC (2007/47/EEC) IVD 98/79/EEC MDR (EU) 2017/745

All offers and deliveries are subject to our sales conditions registered with the Chamber of Commerce in Utrecht.

Bank: Rabobank IBAN: NL 42 RABO 0310 66 10 05 (SWIFT: RABONL2U). KvK nr. 30079112. BTW / VAT / MwSt. / TVA nr. NL 0093 156 88 B 01