

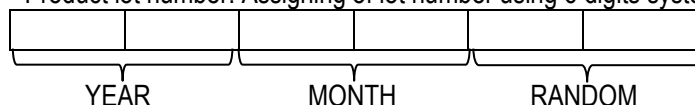
ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	11 March 2024	
Product	Gynaecological Gloves, sterile Ref: GYN-6.5 (S) / GYN-7.5 (M) / GYN-8.5 (L)	
Brand	ROMED	
Classification (MDD, Annex IX)	IIa	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	

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 and Standards. All supporting documentation is retained under the premises of the manufacturer.

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



DIRECTIVES

General applicable directives

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by council directive MDD 2007/47/EC
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 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director