VAN OOSTVEEN MEDICAL B.V.

MEDICAL DISPOSABLES



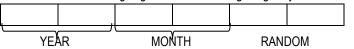
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ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101
	Herenweg 269	Fax: 31-297-288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	Website : www.romed.nl
SRN	NL-MF-000003481	
Product	Finger Condoms (Fingercots)	
	Size: small, medium, large and x-large	
	Ref: FC-S/M/L/XL	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CATI	
UMDNS	11719	
GMDN	11719	
Basic UDI-DI	871720243MDIFCLDN000001W3	

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.

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



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 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