

ROMED HOLLAND Declaration of Conformity

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	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)	CAT I	
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:

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 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.

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