

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	External catheters, Silicone, Male Size: medium, large and x-large Ref: ECSIL – M / L / XL	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
UMDNS	10765	
GMDN	34929	
Basic UDI-DI	871720243MDICATHSEN0001NB	

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.

General applicable directives and regulations

REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Applicable standards

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2016, EN 1041:2008+A1:2013.

No EU common specifications are applicable.

Wilnis, The Netherlands, 21 May 2021

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director