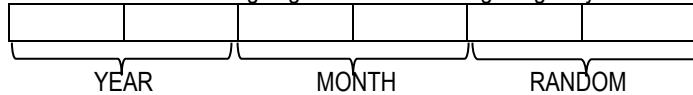


## ROMED HOLLAND Declaration of Conformity

<b>Manufacturer</b>	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 31-297-282 101 Fax: 31-297-288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website : <a href="http://www.romed.nl">www.romed.nl</a>
<b>SRN</b>	NL-MF-000003481	
<b>Product</b>	Surgical isolation gown disposable non-woven REF ISO-GOWN-SMS-[size], ISO-GOWN-DISP-[size]	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	15223	
<b>GMDN</b>	35091	
<b>Basic UDI-DI</b>	871720243MDIGSDN0000001WB	

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 13795-1:2019, ISO 22610:2006, ISO 22612:2005, ISO 29073-3:1996, ISO 13938-1:1999, ISO 811:2018, AATCC 42:2017, AATCC 127:2017, 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