VAN OOSTVEEN MEDICAL B.V.
MEDICAL DISPOSABLES

Romed®

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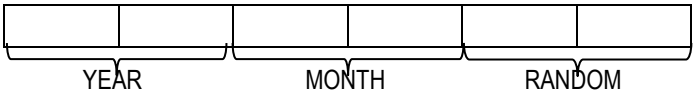
ROMED HOLLAND
Declaration of Conformity

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	Medical examination gloves, non-sterile, powderfree, green Ref: 200AV-A, 205AV-A, 210AV-A, 215AV-A	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	
GMDN	47176	
Basic UDI-DI	871720243MDIGLVPFEN00013J	

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 455-1:2020, 2:2015, 3:2015, 4:2009, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN 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