

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
Product	Polyethylene Aprons Ref: 21/60, 21/60-B, 21/60-100, 1/60 and 1/60-LW	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

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
Product	Polyethylene Coat Aprons Ref: 21/60-CA	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Product	PVC Boots, white REF: BOOTS-WHITE-39, BOOTS-WHITE-40, BOOTS-WHITE-41, BOOTS-WHITE-42, BOOTS-WHITE-43, BOOTS-WHITE-44	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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 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	

DIRECTIVES

General applicable directives :

Regulation (EU) 2016/425 on personal protective equipment of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Applicable standards :

EN ISO 20347:2012

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director

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
Product	Bouffant Caps (white / blue / green) Ref: BOCAP-W/-B/-G	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Product	Protective Coveralls, Disposable, Non-Woven REF: COVE-D-[size]	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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 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	

DIRECTIVES

General applicable directives :

Regulation (EU) 2016/425 on personal protective equipment of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director

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
Product	Disposable bib, with pocket Ref: BIB-1000	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 07 February 2024

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Product	Reusable Protective Face Shield Set And Spare Foil Set REF: COV-SHIELD, COV-SHIELD-5	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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

YEAR		MONTH		RANDOM	

DIRECTIVES

General applicable directives :

Regulation (EU) 2016/425 on personal protective equipment of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director

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.

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

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	Latex examination gloves, non-sterile, Powder free, Ref: 336/341/346/351/356	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	
GMDN	47172	
Basic UDI-DI	871720243MDIGLLPFEN0001U9	

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

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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

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	Latex examination gloves, non-sterile, Pre powdered, Ref: 335/340/345/350/355	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	
GMDN	47173	
Basic UDI-DI	871720243MDIGLLPEN0001ZK	

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

ROMED HOLLAND Declaration of Conformity

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

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	Nitril Examination Gloves (non-sterile) Powderfree, blue and black Ref: NT800/NT805/NT810/NT815 (blue, 3 mils) Ref: NT800-20/NT805-20/NT810-20/NT815-20 (blue, 2 mils) Ref: NTB-800/NTB-805/NTB-810/NTB-815 (black, 3 mils)	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	
GMDN	56286	
Basic UDI-DI	871720243MDIGLNPFFEN0001VP	

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

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	Nitril Examination Gloves (non-sterile) Powderfree, blue, purple and black Ref: NT800/NT805/NT810/NT815 (blue, 3 mils) Ref: NT800-20/NT805-20/NT810-20/NT815-20 (blue, 2 mils) Ref: NTP795/800/805/810/815 (purple) Ref: NTB-800/NTB-805/NTB-810/NTB-815 (black, 3 mils)	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I (blue, black), CAT III (purple)	
UMDNS	11882	
GMDN	56286	
Basic UDI-DI	871720243MDIGLNPEN0001VP	

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

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 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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, 18 October 2022

Signed on behalf of Van Oostveen Medical BV



VAN OOSTVEEN MEDICAL B.V.

MEDICAL DISPOSABLES

M.J. van Oostveen
Managing Director

Romed[®]

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

Romed[®]

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

ROMED HOLLAND Declaration of Conformity

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

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	Romed Nitrile Examination Gloves Purple Powder Free Extra Safe ® Ref: NTP795/800/805/810/815	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT III	
UMDNS	11882	
GMDN	56286	
Basic UDI-DI	871720243MDIGLNPEN0001VP	

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.

The Romed Nitrile Examination Gloves Purple Powder Free Extra Safe:

- is identical to the PPE Regulation 2016/425 which is the subject of EU Type Examination certificate of conformity No. 060/2018/0111 issued by Centexbel Gent, Technologiepart 70, 9052 Zwijanaarde, Belgium
- is subject to the procedure set out in Module D of PPE Regulation 2016/425 under the supervision of the notified body SGS Fimko OY, P.O. Box 30 (Sarkiniementie 3), 00211 Helsinki, Finland.
- Certificate : MY18/1102977932

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

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	NIT-ROMED examination gloves, powder free, non-sterile Ref: NITROM-800, NITROM-805, NITROM-810, NITROM-815	
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:

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

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	Soft+ Latex free examination gloves, non-sterile, powderfree Ref: 101, 106, 111, 116	
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:

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

ROMED HOLLAND Declaration of Conformity

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

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	Stretch vinyl examination gloves, powder free, non-sterile Ref: 200-WP, 205-WP, 210-WP, 215-WP	
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:

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

ROMED HOLLAND Declaration of Conformity

Herenweg 269
3648 CH Wilnis
The Netherlands
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Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

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	Vinyl examination gloves, powder free, non-sterile Ref: 201-S, 206-S, 211-S, 216-S	
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:

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

ROMED HOLLAND Declaration of Conformity

Herenweg 269
3648 CH Wilnis
The Netherlands
Tel. +31 297 28 21 01
Fax +31 297 28 83 16
E-mail info@romed.nl
www.romed.nl

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	Vinyl examination gloves, prepowdered, non-sterile Transparent, Ref: 200, 205, 210, 215 Blue, Ref: 200BB, 205BB, 210BB, 215BB	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	
GMDN	47177	
Basic UDI-DI	871720243MDIGLVPPEN00018U	

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 455-1:2020, -2:2015, -3:2015, -4:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN 420:2003+A1:2009, EN ISO 21420:2020, EN 16523-1:2015+A1:2018, 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

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	31 December 2028	
Product	Gynaecological Gloves, sterile Ref: GYN-6.5 (S) / GYN-7.5 (M) / GYN-8.5 (L)	
Brand	ROMED	
Classification (MDD, Annex IX)	IIa	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	

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 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	

DIRECTIVES

General applicable directives

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by council directive MDD 2007/47/EC
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 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 19 March 2024



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	31 December 2028	
Product	Latex examination gloves, sterile Ref 500/505/510 (per piece) Ref 700/705/710 (per pair)	
Brand	ROMED	
Classification (MDD, Annex IX)	IIa	
Classification (PPE, article 19)	CAT I	
UMDNS	11882	

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	

DIRECTIVES AND REGULATIONS

General applicable directives and regulations

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by council directive MDD 2007/47/EC
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 420:2003+A1:2009, EN ISO 21420:2020, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 20 March 2024



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID number	0044	
Validity of this Declaration of Conformity until	31 December 2028	
Product	Latex surgical gloves, sterile, powdered Ref: OPST060/065/070/075/080/085/090	
Brand	ROMED	
Classification (MDD, Annex IX)	IIa	
Classification (PPE, article 19)	CAT I	
UMDNS	11883	

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 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			

DIRECTIVES

General applicable directives and regulations

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) according to Annex II as amended by council directive MDD 2007/47/EC 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, ISO 10282:2014, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 04 June 2024



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	31 December 2028	
Product	Latex surgical gloves, sterile, powderfree Ref: SGPF-006/065/007/075/008/085/009	
Brand	ROMED	
Classification (MDD, Annex IX)	IIa	
Classification (PPE, article 19)	CAT I	
UMDNS	11883	

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 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	

DIRECTIVES

General applicable directives and regulations

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) according to Annex II as amended by council directive MDD 2007/47/EC 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, ISO 10282:2014, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 03 November 2022



M.J. van Oostveen
Managing Director

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, 205AV, 210AV, 215AV	
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:

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 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

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

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: 200-AV, 205-AV, 210-AV, 215-AV	
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:

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 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

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

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:

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 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

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

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Validity of this Declaration of Conformity until	11 March 2024	
Product	Polyethylene Gloves Ref: 61/60, 65/65, 65/65-LW	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

We, with sole responsibility in drawing up this Declaration of Conformity, declare that the above mentioned product meets the provisions of the manufacturer. 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	

DIRECTIVES

General applicable directives

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Product specifications are according to standards applied by Van Oostveen Medical B.V.

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Validity of this Declaration of Conformity until	11 March 2024	
Product	Examination gloves, non-sterile, powderfree, white Ref 200WP, 205WP, 210WP, 215WP	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

We, with sole responsibility in drawing up this Declaration of Conformity, declare that the above mentioned product meets the provisions of the manufacturer. 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	

DIRECTIVES

General applicable directives :

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Product specifications are according to standards applied by Van Oostveen Medical B.V.

Wilnis, The Netherlands, 03 November 2022



M.J. van Oostveen
Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Validity of this Declaration of Conformity until	11 March 2024	
Product	Isolation Gown, Disposable, Non-Woven, Yellow REF ISO-GOWN-YELLOW	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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 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	

DIRECTIVES

General applicable directives

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

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director

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	Overalls with capuchin, non-woven Ref: OVE- S / M / L / XL / XXL	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	15223	
GMDN	58390	
Basic UDI-DI	871720243MDIOWCHN000001LW	

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

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
Product	Shoe Covers, non woven, with anti slip Ref: SC-1000-NWAS	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

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
Product	Shoe Covers Non-woven Ref: SC-NW-BL-1200	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen

Managing Director

ROMED HOLLAND

Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: info@romed.nl Website: www.romed.nl
Product	Disposable PE shoe covers REF: SC-10000, SC-10000-100	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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 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	

DIRECTIVES

General applicable directives :

Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen
Managing Director

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
Product	Shoe Covers, PE Ref: SC-2000	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

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
Product	Sleeve covers, blue, PE REF: SLEEVE-B	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

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
Product	Sleeve covers, white, non-woven REF: SLEEVE-WD-NW	
Brand	ROMED	
Classification (PPE, article 19)	CAT I	

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) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

Wilnis, The Netherlands, 11 October 2023

Signed on behalf of Van Oostveen Medical BV



M.J. van Oostveen
Managing Director

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	Surgical isolation gown disposable non-woven REF ISO-GOWN-SMS-[size], ISO-GOWN-DISP-[size]	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	15223	
GMDN	35091	
Basic UDI-DI	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:

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 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

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	Visitor Coats Ref: VC-L / XL / XXL	
Brand	ROMED	
Classification (MDR, Annex VIII)	Class I	
Classification (PPE, article 19)	CAT I	
UMDNS	15223	
GMDN	58390	
Basic UDI-DI	871720243MDIVCNWHN0000133	

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