

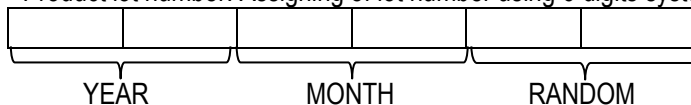
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
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:



### 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

<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>	Bouffant Caps (white / blue / green) Ref: BOCAP-W/-B/-G	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	13882	
<b>GMDN</b>	32297	
<b>Basic UDI-DI</b>	871720243MDIBCPEDN0000148	

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

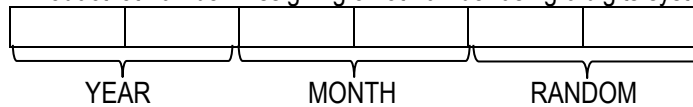
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 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>
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:



### 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

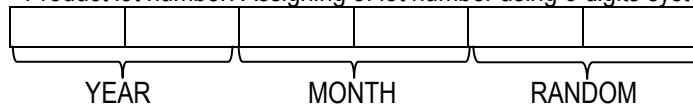
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 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>
Product	Reusable Protective Face Shield Set And Spare Foil Set REF: COV-SHIELD, COV-SHIELD-5	
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:



### 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

<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>	Finger Condoms (Fingercots) Size: small, medium, large and x-large Ref: FC-S/M/L/XL	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11719	
<b>GMDN</b>	11719	
<b>Basic UDI-DI</b>	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

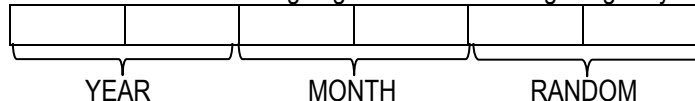
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 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>
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	11 March 2024	
Product	Copolymer examination gloves, sterile Ref: GL-1366, GL-1367, GL-1368	
Brand	ROMED	
Classification (MDD, Annex IX)	<b>I (sterile)</b>	
Classification (PPE, article 19)	<b>CAT I</b>	
UMDNS	<b>11882</b>	

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:



### 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 11137-1:2015, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 3 November 2022



M.J. van Oostveen  
Managing Director

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

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

<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>	Latex examination gloves, non-sterile, Pre powdered, Ref: 335/340/345/350/355	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	47173	
<b>Basic UDI-DI</b>	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](mailto:info@romed.nl)  
[www.romed.nl](http://www.romed.nl)

<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>	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)	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	56286	
<b>Basic UDI-DI</b>	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

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](mailto:info@romed.nl)  
[www.romed.nl](http://www.romed.nl)

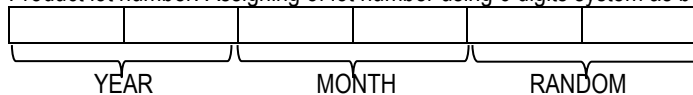
<b>Manufacturer</b>	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 31-297-282 101 Fax: 31-297-288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website : <a href="http://www.romed.nl">www.romed.nl</a>
<b>SRN</b>	NL-MF-000003481	
<b>Product</b>	Romed Nitrile Examination Gloves Purple Powder Free Extra Safe ® Ref: NTP795/800/805/810/815	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT III	
<b>UMDNS</b>	11882	
<b>GMDN</b>	56286	
<b>Basic UDI-DI</b>	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:



### 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.

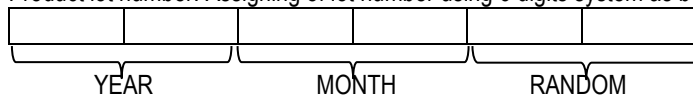
Bank: Rabobank IBAN: NL 42 RABO 0310 66 10 05 (SWIFT: RABONL2U). KvK nr. 30079112. BTW / VAT / MwSt. / TVA nr. NL 0093 156 88 B 01

## ROMED HOLLAND Declaration of Conformity

<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>	NIT-ROMED examination gloves, powder free, non-sterile Ref: NITROM-800, NITROM-805, NITROM-810, NITROM-815	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	47176	
<b>Basic UDI-DI</b>	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 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



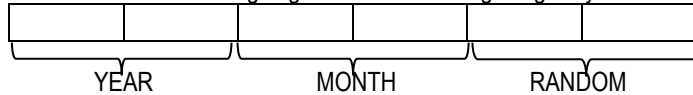
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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>	Soft+ Latex free examination gloves, non-sterile, powderfree Ref: 101, 106, 111, 116	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	47176	
<b>Basic UDI-DI</b>	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 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

<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>	Stretch vinyl examination gloves, powder free, non-sterile Ref: 200-WP, 205-WP, 210-WP, 215-WP	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	47176	
<b>Basic UDI-DI</b>	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 ISO20417:2021 (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

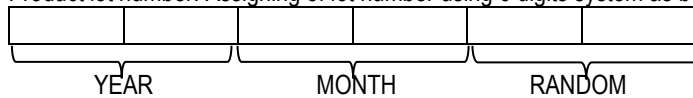
## ROMED HOLLAND Declaration of Conformity

Herenweg 269  
3648 CH Wilnis  
The Netherlands  
Tel. +31 297 28 21 01  
Fax +31 297 28 83 16  
E-mail [info@romed.nl](mailto:info@romed.nl)  
[www.romed.nl](http://www.romed.nl)

<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>	Vinyl examination gloves, powder free, non-sterile Ref: 201-S, 206-S, 211-S, 216-S	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	47176	
<b>Basic UDI-DI</b>	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 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



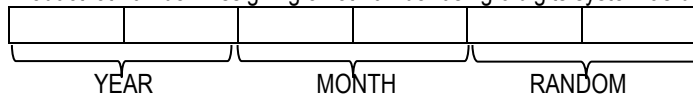
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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>	Vinyl examination gloves, prepowdered, non-sterile Transparent, Ref: 200, 205, 210, 215 Blue, Ref: 200BB, 205BB, 210BB, 215BB	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	11882	
<b>GMDN</b>	47177	
<b>Basic UDI-DI</b>	871720243MDIGLVPEN00018U	

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 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

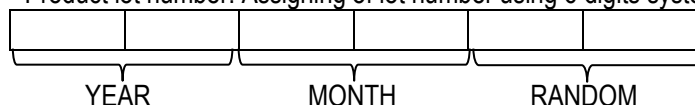
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	11 March 2024	
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:



### 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, 3 November 2022



M.J. van Oostveen  
Managing Director



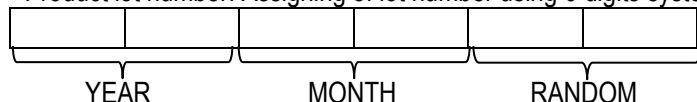
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	11 March 2024	
Product	Latex examination gloves, sterile Ref 500/505/510 (per piece) Ref 700/705/710 (per pair)	
Brand	ROMED	
Classification (MDD, Annex IX)	<b>I sterile</b>	
Classification (PPE, article 19)	<b>CAT I</b>	
UMDNS	<b>11882</b>	

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:



### 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, 03 November 2022



M.J. van Oostveen  
Managing Director

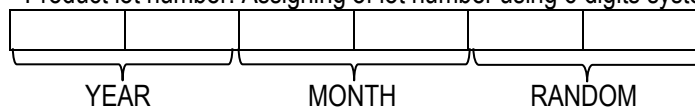
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID number	0044	
Validity of this Declaration of Conformity until	11 March 2024	
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:



### 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 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 03 November 2022



M.J. van Oostveen  
Managing Director

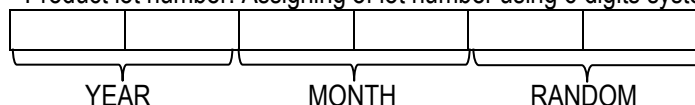
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 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>
Notified Body	TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany	
Notified Body ID Number	0044	
Validity of this Declaration of Conformity until	11 March 2024	
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:



### 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 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

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

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

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

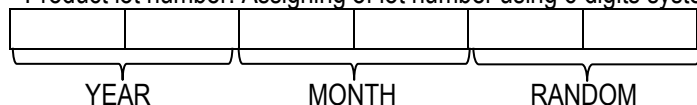
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
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:



### 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

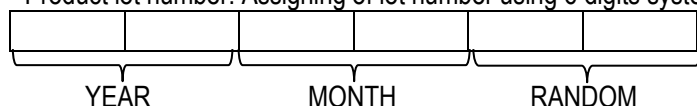
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
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:



### 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



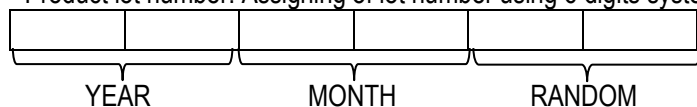
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <a href="mailto:info@romed.nl">info@romed.nl</a> Website: <a href="http://www.romed.nl">www.romed.nl</a>
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:



### 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

<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>	Overalls with capuchin, non-woven Ref: OVE- S / M / L / XL /XXL	
<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>	58390	
<b>Basic UDI-DI</b>	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:



### 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



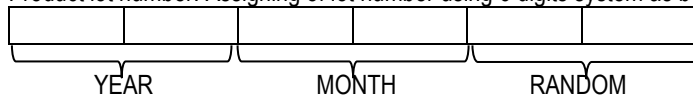
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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>	Shoe Covers, non woven, with anti slip Ref: SC-1000-NWAS	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	13574	
<b>GMDN</b>	15056	
<b>Basic UDI-DI</b>	871720243MDISHCNWASDN01EH	

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 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



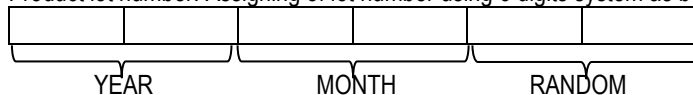
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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>	Shoe Covers Non-woven Ref: SC-NW-BL-1200	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	13574	
<b>GMDN</b>	15056	
<b>Basic UDI-DI</b>	871720243MDISHCNWDN00015B	

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 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

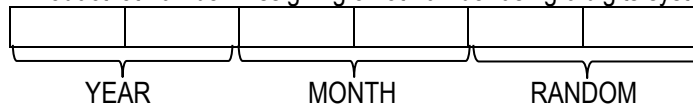
# ROMED HOLLAND

## Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 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>
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:



### 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



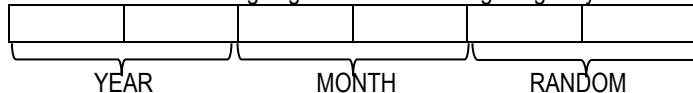
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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>	Shoe Covers, PE Ref: SC-2000	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	13574	
<b>GMDN</b>	15056	
<b>Basic UDI-DI</b>	871720243MDISHCCPEDN001WA	

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 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

<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>	Sleeve covers, blue, PE REF: SLEEVE-B	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	15571	
<b>GMDN</b>	61939	
<b>Basic UDI-DI</b>	871720243MDISLCPEDN0001YG	

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



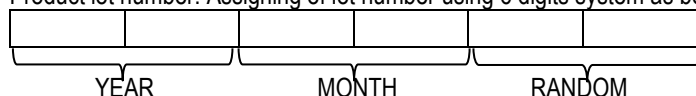
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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>	Sleeve covers, white, non-woven REF: SLEEVE-WD-NW	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	15571	
<b>GMDN</b>	61939	
<b>Basic UDI-DI</b>	871720243MDISLCNWDN00018X	

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 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

<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>	Snood caps (white) REF: SN-CAP-W	
<b>Brand</b>	ROMED	
<b>Classification (MDR, Annex VIII)</b>	Class I	
<b>Classification (PPE, article 19)</b>	CAT I	
<b>UMDNS</b>	13882	
<b>GMDN</b>	32297	
<b>Basic UDI-DI</b>	871720243MDISNCNWDN001AR	

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 13934-1:2013, 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



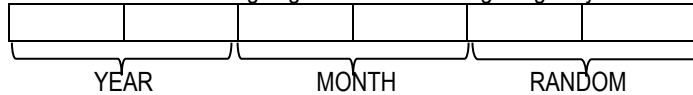
M.J. van Oostveen  
Managing Director

## ROMED HOLLAND Declaration of Conformity

<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



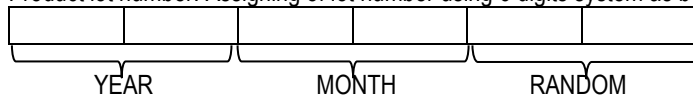
M.J. van Oostveen  
Managing Director

## 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>	Visitor Coats Ref: VC-L / XL / XXL	
<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>	58390	
<b>Basic UDI-DI</b>	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:



### 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