Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101
	Herenweg 269	Fax: 31-297-288316
	3648 CH Wilnis	E-mail: <u>info@romed.nl</u>
	Netherlands	Website : <u>www.romed.nl</u>
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.

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 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
Product	Polyethylene Coat Aprons	Polyethylene Coat Aprons	
	Ref: 21/60-CA	Ref: 21/60-CA	
Brand	ROMED	ROMED	
Classification (PPE, article 19)	CATI	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

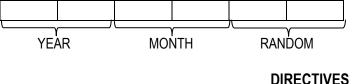
REGULATION (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

M.J. van Oostveen Managing Director

Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101
	Herenweg 269	Fax: 0031 297 288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	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)	CATI	

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:



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



Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101
	Herenweg 269	Fax: 31-297-288316
	3648 CH Wilnis	E-mail: <u>info@romed.nl</u>
	Netherlands	Website : <u>www.romed.nl</u>
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	мойтн	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.

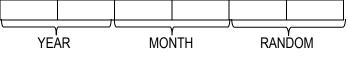


M.J. van Oostveen Managing Director

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis Netherlands	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <u>info@romed.nl</u> 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:



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



Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
Product	Disposable bib, with pocket	Disposable bib, with pocket	
	Ref: BIB-1000	Ref: BIB-1000	
Brand	ROMED		
Classification (PPE, article 19)	CATI	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.

M.J. van Oostveen Managing Director

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

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:

	τ	
YEAR	моитн	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

MEDICAL DISPOSABLES

Romed

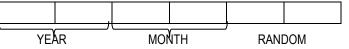
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Finger Condoms (Fingercots)		
	Size: small, medium, large and x-large	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)	CATI		
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:



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

MEDICAL DISPOSABLES

Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: <u>info@romed.nl</u>	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Latex examination gloves, non-steri	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)	CATI		
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	мойтн	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

MEDICAL DISPOSABLES

Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Tel: 31-297-282 101			
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
SRN	NL-MF-000003481			
Product	Latex examination gloves, non-sterile,	Latex examination gloves, non-sterile, Pre powdered,		
	Ref: 335/340/345/350/355			
Brand	ROMED	ROMED		
Classification (MDR, Annex VIII)	Class I			
Classification (PPE, article 19)	CAT I			
UMDNS	11882			
GMDN	47173			
Basic UDI-DI	871720243MDIGLLPPEN0001ZK			

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	мойтн	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

MEDICAL DISPOSABLES

Romed

ROMED HOLLAND Declaration of Conformity

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

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
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)	CATI		
UMDNS	11882		
GMDN	56286		
Basic UDI-DI	871720243MDIGLNPFEN0001VP		

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:

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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

L

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

MEDICAL DISPOSABLES

Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Nitril Examination Gloves (non-sterile)	
	Powderfree, blue, purple and black		
	Ref: NT800/NT805/NT810/NT815 (bl	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	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	871720243MDIGLNPFEN0001VP		

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.



MEDICAL DISPOSABLES

M.J. van Oostveen Managing Director Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

Romed

MEDICAL DISPOSABLES

Romed

ROMED HOLLAND Declaration of Conformity

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

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
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	871720243MDIGLNPFEN0001VP		

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, Techniologiepart 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:

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YĘ	AR	МО	NTH	RANE	Вом

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

MEDICAL DISPOSABLES

Romed

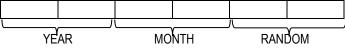
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	NIT-ROMED examination gloves, powde	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:



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

MEDICAL DISPOSABLES

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ROMED HOLLAND Declaration of Conformity

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

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Soft+ Latex free examination gloves, non-	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:



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

MEDICAL DISPOSABLES

Romed

ROMED HOLLAND Declaration of Conformity

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

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
SRN	NL-MF-000003481	NL-MF-000003481		
Product	Stretch vinyl examination gloves, powde	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 ISO20417:2021 (cor. 2021-12).

No EU common specifications are applicable.

M.J. van Oostveen Managing Director

MEDICAL DISPOSABLES

ROMED HOLLAND Declaration of Conformity

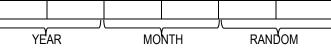
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

Rome

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
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:



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.

M.J. van Oostveen Managing Director

MEDICAL DISPOSABLES

Romed

ROMED HOLLAND Declaration of Conformity

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

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Vinyl examination gloves, prepowdered, r	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:

	/			//	
ΥĔ	AR	МО	NTH	RANE	Вом

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.



M.J. van Oostveen

Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101	
	Herenweg 269	Fax: 0031 297 288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website: www.romed.nl	
Notified Body	TÜV NORD CERT GmbH, Am	n 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)	lla		
Classification (PPE, article 19)	CATI		
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:

۲ YE	AR	MON	n NTH	RAN	ү DOM

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

t

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.

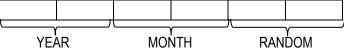
Wilnis, The Netherlands, 19 March 2024



Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101	
	Herenweg 269	Fax: 0031 297 288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website: www.romed.nl	
Notified Body	TÜV NORD CERT GmbH, An	n 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)	lla		
Classification (PPE, article 19)	CATI		
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:



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



Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101	
	Herenweg 269	Fax: 0031 297 288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website: www.romed.nl	
Notified Body	TÜV NORD CERT GmbH, Am	n 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)	lla		
Classification (PPE, article 19)	CATI		
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.

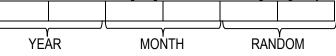
Wilnis, The Netherlands, 04 June 2024



Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101	
	Herenweg 269	Fax: 0031 297 288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website: www.romed.nl	
Notified Body	TÜV NORD CERT GmbH, Am	n 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)	lla		
Classification (PPE, article 19)	CATI		
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 11135:2014, EN ISO 11607-1:2017, EN ISO 15223-1:2021, EN ISO 20417:2021+C1:2021.

Wilnis, The Netherlands, 03 November 2022



MEDICAL DISPOSABLES

Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Tel: 31-297-282 101			
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
SRN	NL-MF-000003481	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:

YEÂR	мойтн	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

MEDICAL DISPOSABLES

Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV Tel: 31-297-282 101			
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
SRN	NL-MF-000003481			
Product		Medical examination gloves, non-sterile, powderfree, green		
	Ref: 200-AV, 205-AV, 210-AV, 215-AV			
Brand	ROMED	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:

YEÂR	мойтн	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

MEDICAL DISPOSABLES

Romed

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

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Medical examination gloves, non-ster	Medical examination gloves, non-sterile, powderfree, green	
	Ref: 200AV-A, 205AV-A, 210AV-A, 215AV-A		
Brand	ROMED	ROMED	
Classification (MDR, Annex VIII)	Class I	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:

YEÂR	МОЙТН	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

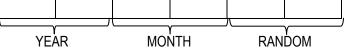


M.J. van Oostveen Managing Director

Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101
	Herenweg 269	Fax: 0031 297 288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	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)	CATI	

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.

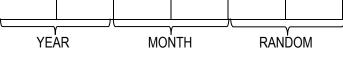
Wilnis, The Netherlands, 3 November 2022



Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101
	Herenweg 269	Fax: 0031 297 288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	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)	CATI	

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

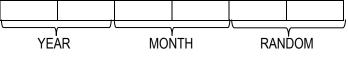


M.J. van Oostveen Managing Director

Manufacturer	Van Oostveen Medical BV	Tel: 0031 297 282101
	Herenweg 269	Fax: 0031 297 288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	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)	CATI	

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

MEDICAL DISPOSABLES

Romed

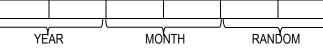
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
SRN	NL-MF-000003481		
Product	Overalls with capuchin, non-woven	Overalls with capuchin, non-woven	
	Ref: OVE- S / M / L / XL /XXL		
Brand	ROMED		
Classification (MDR, Annex VIII)	Class I		
Classification (PPE, article 19)	CATI	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:



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.



M.J. van Oostveen Managing Director

Romed

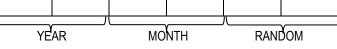
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101
	Herenweg 269	Fax: 31-297-288316
	3648 CH Wilnis	E-mail: <u>info@romed.nl</u>
	Netherlands	Website : <u>www.romed.nl</u>
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:



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.

M.J. van Oostveen Managing Director

Romed

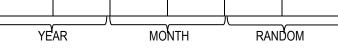
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101
	Herenweg 269	Fax: 31-297-288316
	3648 CH Wilnis	E-mail: info@romed.nl
	Netherlands	Website : <u>www.romed.nl</u>
Product	Shoe Covers Non-woven	
	Ref: SC-NW-BL-1200	
Brand	ROMED	
Classification (PPE, article 19)	CATI	

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

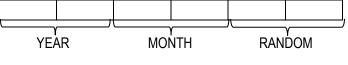
REGULATION (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment.

M.J. van Oostveen Managing Director

Manufacturer	Van Oostveen Medical BV Herenweg 269 3648 CH Wilnis	Tel: 0031 297 282101 Fax: 0031 297 288316 E-mail: <u>info@romed.nl</u>
	Netherlands	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:



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



Romed

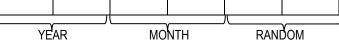
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
Product	Shoe Covers, PE			
	Ref: SC-2000			
Brand	ROMED			
Classification (PPE, article 19)	CATI			

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

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 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
Product	Sleeve covers, blue, PE			
	REF: SLEEVE-B			
Brand	ROMED			
Classification (PPE, article 19)	CATI			

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:

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1						

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

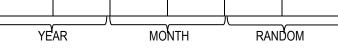
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
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:



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.

M.J. van Oostveen Managing Director

MEDICAL DISPOSABLES

Romed

ROMED HOLLAND Declaration of Conformity

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

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101	
	Herenweg 269	Fax: 31-297-288316	
	3648 CH Wilnis	E-mail: info@romed.nl	
	Netherlands	Website : <u>www.romed.nl</u>	
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)	CATI		
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:



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

MEDICAL DISPOSABLES

Romed

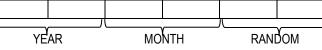
Herenweg 269 3648 CH Wilnis The Netherlands Tel. +31 297 28 21 01 Fax +31 297 28 83 16 -mail info@romed.nl www.romed.nl

ROMED HOLLAND Declaration of Conformity

Manufacturer	Van Oostveen Medical BV	Tel: 31-297-282 101		
	Herenweg 269	Fax: 31-297-288316		
	3648 CH Wilnis	E-mail: info@romed.nl		
	Netherlands	Website : <u>www.romed.nl</u>		
SRN	NL-MF-000003481	NL-MF-000003481		
Product	Visitor Coats			
	Ref: VC-L / XL / XXL			
Brand	ROMED			
Classification (MDR, Annex VIII)	Class I			
Classification (PPE, article 19)	CATI	CATI		
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:



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.



M.J. van Oostveen Managing Director