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TOP QUALITY, TOP EFFICIENCY

TG MEDICAL SDN. BHD.
The World's Largest Manufacturer of Gloves
GOOD HEALTH, SAFETY FIRST & BE HONEST

Registration No.
199301028620 (283358-W)
SST ID: B10-1808-22000011

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

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BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.
FACILITIES : 50 Factories (Malaysia, Thailand, Vietnam & China), 800 Production Lines, 100 Billion Gloves Per Annum, 22,000 Employees.
MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY (DoC)

Name of Device: Sterile Latex Surgical Powder Free Glove

Manufacturing Site

TG Medical Sdn. Bhd.

Lot 5091, Jalan Teratai, Batu 5, Off Jalan Meru,

41050, Klang, Selangor D.E., Malaysia

MDR 2017/745

Single Registration Number	: MY-MF-000009606 (Manufacturing Site SRN)
European Authorized Representative	: Top Glove Europe GmbH Bliersheimer Str. 80, D-47229 Duisburg, Germany.
Single Registration Number	: DE-AR-000004968 (EAR SRN)
Classification Rule	: Rule 7, Class IIa
Conformity Assessment Procedure	: Annex IX (Chapter I)
Brand	: MUMU
Basic UDI – DI	: 955583990800Q3
EC Certificate(s) number	: MY24/00000440
EC Certificate(s) valid until	: 27 September 2029
Notified Body	: SGS Belgium NV, SGS House Noorderlaan, 872030 Antwerp Belgium
CE Marking	: CE 1639
Applicable Standards	: Attachment I

Intended use: Sterile Latex Surgical Powder Free Glove is intended to be worn by operating room personnel to prevent the transmission of infections or cross contamination between patient and user.

Conclusion:

This declaration of conformity is issued under the sole responsibility of TG Medical Sdn. Bhd. We hereby declare that the medical device (s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is also supported by the Quality Management System approval to ISO 13485 issued by SGS Belgium NV. All supporting documentation is retained at the premises of the manufacturer.

DoC Validity Date	: 4th December 2024 until 3rd December 2027
Shipment Territory	: Turkey

Name: Pn Noor Akilah Saidin
Designation: General Manager, RA
Date: 4th December 2024

ATTACHMENT I: LIST OF APPLICABLE STANDARDS AND REFERENCE FOR MDR 2017/745

Applicable Standards:

No	Standard	Descriptions	Date Published
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	March 2016
2	EN 455-1:2020+A1:2022	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
3	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
4	EN 455-3:2023	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation	April 2015
5	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	October 2009
6	EN ISO14971:2019/A11:2021	Medical device - Application of risk management to medical devices.	December 2021
7	ISO 2859-1:2011	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
8	EN ISO 11737-1:2018/ A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	June 2021
9	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	May 2020
10	EN ISO 11137-1:2015/ A2:2019	Sterilization of health care products – Requirements for validation and routine control–Radiation sterilization	November 2019
11	EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	June 2015

No	Standard	Descriptions	Date Published
12	EN ISO 10993-1:2020	Biological evaluation for medical device – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018)	December 2020
13	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	June 2009
14	EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)	August 2013
15	EN ISO 10993-11:2018	Biological evaluation of medical devices. Test for systemic toxicity (ISO 10993-11:2017)	May 2018
16	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	June 2021
17	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	March 2021
18	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	January 2020
19	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	January 2020
20	EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	September 2021
21	EN 62366-1/A1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices	August 2020
22	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	May 2021
23	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	July 2020
24	ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems	April 2016
25	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
26	MDR 2017/745 (Annex I)	Technical Documentation	April 2017
27	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017

No	Standard	Descriptions	Date Published
28	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
30	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
31	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
32	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
33	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
34	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017

User Manual of Natural Rubber Surgical Gloves

Version:V1.2

Date:2023-3-31

Manufacturer (name and address):	Guilin HBM Health Protections, Inc. No. 1-2, Shuijing East Road, Economic and technological Development Area, Guilin, 541805, China Tel: 86-773-2550119 Email: export@hbmchina.com
EC Representative (name and address):	HBM Medical Coliemore House, Coliemore Road, Dalky, Co. Dublin, A96 A8D5, Ireland Tel: 0044 7709045852 Email: maurice@4shbm.com

1. Device Identification:

Proprietary Name:	Medispo Essential natural rubber latex surgical gloves powder free
Common Name:	Single-use sterile natural rubber surgical gloves
Device Class	Ⅱa as per EU MDR 2017/745
Rule	Rule 6 as per EU MDR 2017/745
CE 2797	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.

2. Indication for Use:

The NR Surgical Gloves is a disposable device that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contamination

The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are designed to be worn by operating room personnel. The NR Surgical Gloves are designed for use in the environments within hospitals and other healthcare facilities.

3. Device Description:

The Medispo Natural Rubber Surgical Gloves are made of natural rubber latex, based on the technology of "latex dipping", similar to that for making latex condoms. The gloves are anatomical in structure, either smooth- or texture-surfaced, with or without a rolled rim at the cuff. They come in nine sizes (5.5",6", 6.5", 7", 7.5", 8", 8.5", 9",9.5") to suit different users, all sharing the same color, creamy white.

The gloves are powder-free, meaning that no powder is incorporated for purposes other than manufacturing, from which only residual powder is left with the final finished product. To attain easy donning, the technique of "polymer coating" is employed to coat the gloves' inside surface with a thin, smooth layer of polymer, polyurethane.

The gloves are radiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6} and are packaged in sterility maintenance packages to ensure a shelf life of 3 years.They are limited to single use only, and repeated use or repeated sterilization is not allowed in surgical application.

4. Specifications

4.1 Dimensions (Length & width & single wall thickness, mm)

The dimensions of the gloves comply with the requirement in the following table:

Size	*Length*	*Width*	*Thickness*
5.5	250mm min	72±4mm	0.12mm min
6	260mm min	77±5mm	
6.5	260mm min	83±5mm	
7	270mm min	89±5mm	
7.5	270mm min	95±5mm	
8	270mm min	102±6mm	
8.5	280mm min	108±6mm	
9	280mm min	114±6mm	
9.5	280mm min	121±6mm	

The compliance level is an AQL of 4.0.

4.2 Strength

The force at break of the gloves (median of 13 gloves) is not less than 9.0N.

4.3 Watertightness

The gloves are so designed and manufactured that they have adequate watertightness and are free from holes to function as a barrier against microorganism transmission. The compliance level is an AQL of 0.65.

4.4 Residue powder content： ≤ 2.0mg/glove

4.5 Leachable proteins： ≤200μg/g

4.5 Sterility

The gloves are provided pre-sterilized, using ionizing radiation to acheive a SAL of 10^{-6}.

The periodc documented validation of the effectiveness of the sterilization method and audit of the appropriateness of the established radiation dose is conducted in accordance with ISO 11137-1 and -2 to ensure the sterilization activity is reliable and reproducible.

5. Types

Where their finish is concerned, the gloves are divided into two types, smooth and textured. The former is smooth all over, whereas the latter has a textured area covering the palm and the front part of the thumb and fingers.

In terms of how the cuff is formed, the gloves also have two types, cuffed and uncuffed. A cuffed glove has a rolled rim at the cuff, and an uncuffed one does not.

6. Packaging:

The gloves, with their wrists turned inside out, are placed in pairs into paper wrappers, which are then packaged in paper or poly pouches. After being sealed by the sealing machine, the pouches are put into boxes, which are then packed into outer cartons prior to sterilization.

The effectiveness of the sealing process is periodically validated in accordance to ISO 11607-2 to ensure that sterile barrier system integrity is attained in a reliable and reproducible manner.

7. Shelf life:

The Medispo Natural Rubber Surgical Gloves have a claimed shelf life of 3 years at 25℃ based on the accelerated aging study data.

8. Biocompatibility

The Medispo Natural Rubber Surgical Gloves have undergone various relevant biological tests, including skin irritation test, sensitization test, *in vitro* cytotoxicity test, material mediated pyrogenicity test, acute systemic toxicity test, and heamolysis test, in accordance with ISO 10993 series. The data generated from the tests

collectively support the conclusion that the gloves have good biocompatibility and are safe to both users and patients when used according to their intended application.

9. Instruction for use:

- Please use before the expiry date as indicated by package labeling.
- Select the right size that best suits your hands.
- For easy donning, dry your hands if they are wet.
- Avoid any sharp or barbed objects to prevent puncture or cut in the gloves. Trim your fingernails if necessary.
- If the gloves are found broken during use, discard them and use a new pair after hand disinfection.
- Replace the gloves with a new pair if they have been in use for more than 4 hours to prevent the risk of glove damage from increasing.
- Do not expose this product to intense light, such as sunlight or ultraviolet ray.
- Avoid contact with oils, acids, alkalis, or other chemicals that can have damaging effects on rubber.

10. Warning:

- This product contains natural rubber latex which may cause allergic reactions.
- Do NOT use if the sterile package is damaged or unintentionally opened before use.
- This product is disposable and for single use only. Reuse of this product may increase the risk of contamination.
- Dispose of this product as medical waste after use, since the used gloves may be contaminated with potentially infectious substance of human origin.

11. Storage conditions:

Store in a cool, dry, and well-ventilated environment free of any corrosive gases. Shield open boxes from direct sun and fluorescent lighting.

12. Notice:

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

User Manual of Polyisoprene Surgical Gloves

Manufacturer (name and address):	Guilin HBM Health Protections, Inc. No. 1-2, Shuijing East Road, Economic and technological Development Area, Guilin, 541805, China Tel: 86-773-2550119 Email: export@hbmchina.com
EC Representative (name and address):	HBM Medical Coliemore House, Coliemore Road, Dalky, Co. Dublin, A96 A8D5, Ireland Tel: 0044 7709045852 Email: maurice@4shbm.com

1. Device Identification:

Proprietary Name:	Medispo Polyisoprene Surgical Gloves
Common Name:	Single-use sterile polyisoprene surgical gloves
Device Class	IIa as per EU MDR 2017/745
Rule	Rule 6 as per EU MDR 2017/745

2. Indication for Use:

The PI Surgical Gloves is a disposable device that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contamination

The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are designed to be worn by operating room personnel. The PI Surgical Gloves are designed for use in the environments within hospitals and other healthcare facilities.

3. Device Description:

The Medispo Polyisoprene Surgical Gloves are made of polyisoprene rubber latex, based on the technology of "latex dipping", similar to that for making latex condoms. The gloves are anatomical in structure, either smooth- or texture-surfaced, with or without a rolled rim at the cuff. They come in nine sizes (5.5",6", 6.5", 7", 7.5", 8", 8.5", 9",9.5") to suit different users, all sharing the same color, creamy white.

The gloves are powder-free, meaning that no powder is incorporated for purposes other than manufacturing, from which only residual powder is left with the final finished product. To attain easy donning, the technique of "polymer coating" is employed to coat the gloves' inside surface with a thin, smooth layer of polymer, polyurethane.

The gloves are radiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6} and are packaged in

sterility maintenance packages to ensure a shelf life of 3 years.They are limited to single use only, and repeated use or repeated sterilization is not allowed in surgical application.

4. Specifications

4.1 Dimensions (Length & width & single wall thickness, mm)

The dimensions of the gloves comply with the requirement in the following table:

Size	*Length*	*Width*	*Thickness*
5.5	250mm min	72±4mm	Smooth area: 0.10mm min Textured area: 0.13mm min
6	260mm min	77±5mm	
6.5	260mm min	83±5mm	
7	270mm min	89±5mm	
7.5	270mm min	95±5mm	
8	270mm min	102±6mm	
8.5	280mm min	108±6mm	
9	280mm min	114±6mm	
9.5	280mm min	121±6mm	

The compliance level is an AQL of 4.0.

4.2 Strength

The force at break of the gloves (median of 13 gloves) is not less than 9.0N.

4.3 Watertightness

The gloves are so designed and manufactured that they have adequate watertightness and are free from holes to function as a barrier against microorganism transmission. The compliance level is an AQL of 0.65.

4.4 Residue powder content： ≤ 2.0mg/glove

4.5 Sterility

The gloves are provided pre-sterilized, using ionizing radiation to acheive a SAL of 10^{-6}.

The periodc documented validation of the effectiveness of the sterilization method and audit of the appropriateness of the established radiation dose is conducted in accordance with ISO 11137-1 and -2 to ensure the sterilization activity is reliable and reproducible.

5. Types

Where their finish is concerned, the gloves are divided into two types, smooth and textured. The former is smooth all over, whereas the latter has a textured area covering the palm and the front part of the thumb and fingers.

In terms of how the cuff is formed, the gloves also have two types, cuffed and uncuffed. A cuffed glove has a rolled rim at the cuff, and an uncuffed one does not.

6. Packaging:

The gloves, with their wrists turned inside out, are placed in pairs into paper wrappers, which are then packaged in paper or poly pouches. After being sealed by the sealing machine, the pouches are put into boxes, which are then packed into outer cartons prior to sterilization.

The effectiveness of the sealing process is periodically validated in accordance to ISO 11607-2 to ensure that sterile barrier system integrity is attained in a reliable and reproducible manner.

7. Shelf life:

The Medispo Polyisoprene Surgical Gloves have a claimed shelf life of 3 years at 25℃ based on the accelerated aging study data.

8. Biocompatibility

The Medispo Polyisoprene Surgical Gloves have undergone various relevant biological tests, including skin irritation test, sensitization test, *in vitro* cytotoxicity test, material mediated pyrogenicity test, acute systemic toxicity test, and heamolysis test, in accordance with ISO 10993 series. The data generated from the tests collectively support the conclusion that the gloves have good biocompatibility and are safe to both users and patients when used according to their intended application.

9. Instruction for use:

- Please use before the expiry date as indicated by package labeling.
- Select the right size that best suits your hands.
- For easy donning, dry your hands if they are wet.
- Avoid any sharp or barbed objects to prevent puncture or cut in the gloves. Trim your fingernails if necessary.
- If the gloves are found broken during use, discard them and use a new pair after hand disinfection.
- Replace the gloves with a new pair if they have been in use for more than 4 hours to prevent the risk of glove damage from increasing.
- Do not expose this product to intense light, such as sunlight or ultraviolet ray.
- Avoid contact with oils, acids, alkalis, or other chemicals that can have damaging effects on rubber.

10. Warning:

- Do NOT use if the sterile package is damaged or unintentionally opened before use.
- This product is disposable and for single use only. Reuse of this product may increase the risk of contamination.
- Dispose of this product as medical waste after use, since the used gloves may be contaminated with potentially infectious substance of human origin.

11. Storage conditions:

Store in a cool, dry, and well-ventilated environment free of any corrosive gases. Shield open boxes from direct sun and fluorescent lighting.

12. Notice:

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

User Manual of Natural Rubber Surgical Gloves

Version:V1.2

Date:2023-3-31

Manufacturer (name and address):	Guilin HBM Health Protections, Inc. No. 1-2, Shuijing East Road, Economic and technological Development Area, Guilin, 541805, China Tel: 86-773-2550119 Email: export@hbmchina.com
EC Representative (name and address):	HBM Medical Coliemore House, Coliemore Road, Dalky, Co. Dublin, A96 A8D5, Ireland Tel: 0044 7709045852 Email: maurice@4shbm.com

1. Device Identification:

Proprietary Name:	Medispo Premium TPC natural rubber latex surgical gloves powder free
Common Name:	Single-use sterile natural rubber surgical gloves
Device Class	Ⅱa as per EU MDR 2017/745
Rule	Rule 6 as per EU MDR 2017/745
CE 2797	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.

2. Indication for Use:

The NR Surgical Gloves is a disposable device that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contamination

The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are designed to be worn by operating room personnel. The NR Surgical Gloves are designed for use in the environments within hospitals and other healthcare facilities.

3. Device Description:

The Medispo Natural Rubber Surgical Gloves are made of natural rubber latex, based on the technology of "latex dipping", similar to that for making latex condoms. The gloves are anatomical in structure, either smooth- or texture-surfaced, with or without a rolled rim at the cuff. They come in nine sizes (5.5",6", 6.5", 7", 7.5", 8", 8.5", 9",9.5") to suit different users, all sharing the same color, creamy white.

The gloves are powder-free, meaning that no powder is incorporated for purposes other than manufacturing, from which only residual powder is left with the final finished product. To attain easy donning, the technique of "polymer coating" is employed to coat the gloves' inside surface with a thin, smooth layer of polymer, polyurethane.

The gloves are radiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6} and are packaged in sterility maintenance packages to ensure a shelf life of 3 years.They are limited to single use only, and repeated use or repeated sterilization is not allowed in surgical application.

4. Specifications

4.1 Dimensions (Length & width & single wall thickness, mm)

The dimensions of the gloves comply with the requirement in the following table:

Size	*Length*	*Width*	*Thickness*
5.5	280mm min	72±4mm	0.14mm min
6	280mm min	77±5mm	
6.5	280mm min	83±5mm	
7	285mm min	89±5mm	
7.5	285mm min	95±5mm	
8	285mm min	102±6mm	
8.5	290mm min	108±6mm	
9	290mm min	114±6mm	
9.5	300mm min	121±6mm	

The compliance level is an AQL of 4.0.

4.2 Strength

The force at break of the gloves (median of 13 gloves) is not less than 9.0N.

4.3 Watertightness

The gloves are so designed and manufactured that they have adequate watertightness and are free from holes to function as a barrier against microorganism transmission. The compliance level is an AQL of 0.65.

4.4 Residue powder content： ≤ 2.0mg/glove

4.5 Leachable proteins： ≤200μg/g

4.5 Sterility

The gloves are provided pre-sterilized, using ionizing radiation to acheive a SAL of 10^{-6}.

The periodc documented validation of the effectiveness of the sterilization method and audit of the appropriateness of the established radiation dose is conducted in accordance with ISO 11137-1 and -2 to ensure the sterilization activity is reliable and reproducible.

5. Types

Where their finish is concerned, the gloves are divided into two types, smooth and textured. The former is smooth all over, whereas the latter has a textured area covering the palm and the front part of the thumb and fingers.

In terms of how the cuff is formed, the gloves also have two types, cuffed and uncuffed. A cuffed glove has a rolled rim at the cuff, and an uncuffed one does not.

6. Packaging:

The gloves, with their wrists turned inside out, are placed in pairs into paper wrappers, which are then packaged in paper or poly pouches. After being sealed by the sealing machine, the pouches are put into boxes, which are then packed into outer cartons prior to sterilization.

The effectiveness of the sealing process is periodically validated in accordance to ISO 11607-2 to ensure that sterile barrier system integrity is attained in a reliable and reproducible manner.

7. Shelf life:

The Medispo Natural Rubber Surgical Gloves have a claimed shelf life of 3 years at 25℃ based on the accelerated aging study data.

8. Biocompatibility

The Medispo Natural Rubber Surgical Gloves have undergone various relevant biological tests, including skin irritation test, sensitization test, *in vitro* cytotoxicity test, material mediated pyrogenicity test, acute systemic toxicity test, and heamolysis test, in accordance with ISO 10993 series. The data generated from the tests

collectively support the conclusion that the gloves have good biocompatibility and are safe to both users and patients when used according to their intended application.

9. Instruction for use:

- Please use before the expiry date as indicated by package labeling.
- Select the right size that best suits your hands.
- For easy donning, dry your hands if they are wet.
- Avoid any sharp or barbed objects to prevent puncture or cut in the gloves. Trim your fingernails if necessary.
- If the gloves are found broken during use, discard them and use a new pair after hand disinfection.
- Replace the gloves with a new pair if they have been in use for more than 4 hours to prevent the risk of glove damage from increasing.
- Do not expose this product to intense light, such as sunlight or ultraviolet ray.
- Avoid contact with oils, acids, alkalis, or other chemicals that can have damaging effects on rubber.

10. Warning:

- This product contains natural rubber latex which may cause allergic reactions.
- Do NOT use if the sterile package is damaged or unintentionally opened before use.
- This product is disposable and for single use only. Reuse of this product may increase the risk of contamination.
- Dispose of this product as medical waste after use, since the used gloves may be contaminated with potentially infectious substance of human origin.

11. Storage conditions:

Store in a cool, dry, and well-ventilated environment free of any corrosive gases. Shield open boxes from direct sun and fluorescent lighting.

12. Notice:

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

User Manual of Natural Rubber Latex Surgical Gloves

Doc .No.YHS241009B

Manufacturer (name and address):	Guilin HBM Health Protections, Inc. No. 1-2, Shuijing East Road, Economic and technological Development Area, Guilin, 541805, China Tel: 86-773-2550119 Email: export@hbmchina.com
EC Representative (name and address):	HBM Medical Coliemore House, Coliemore Road, Dalky, Co. Dublin, A96 A8D5, Ireland Tel: 0044 7709045852 Email: maurice@4shbm.com

1. Device Identification:

Proprietary Name:	Mumu Natural Rubber Latex Surgical Gloves
Common Name:	Single-use sterile natural rubber surgical gloves
Device Class	Ⅱa as per EU MDR 2017/745
Rule	Rule 7 as per EU MDR 2017/745
CE Notify body number	CE 2797

2. Indication for Use:

The NR Surgical Gloves is a disposable device that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contamination

The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are designed to be worn by operating room personnel. The NR Surgical Gloves are designed for use in the environments within hospitals and other healthcare facilities.

3. Device Description:

The Mumu Natural Rubber Latex Surgical Gloves are made of natural rubber latex, based on the technology of "latex dipping", similar to that for making latex condoms. The gloves are anatomical in structure, either smooth- or texture-surfaced, with or without a rolled rim at the cuff. They come in nine sizes (5.5",6", 6.5", 7", 7.5", 8", 8.5", 9",9.5") to suit different users, all sharing the same color, creamy white.

The gloves are powder-free, meaning that no powder is incorporated for purposes other than manufacturing, from which only residual powder is left with the final finished product. To attain easy donning, the technique of

"polymer coating" is employed to coat the gloves' inside surface with a thin, smooth layer of polymer, polyurethane.

The gloves are radiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6} and are packaged in sterility maintenance packages to ensure a shelf life of 3 years.They are limited to single use only, and repeated use or repeated sterilization is not allowed in surgical application.

4. Specifications

4.1 Dimensions (Length & width & single wall thickness, mm)

The dimensions of the gloves comply with the requirement in the following table:

Size	*Length*	*Width*	*Thickness*
5.5	250mm min	72±4mm	Smooth area: 0.10mm min Textured area: 0.13mm min
6	260mm min	77±5mm	
6.5	260mm min	83±5mm	
7	270mm min	89±5mm	
7.5	270mm min	95±5mm	
8	270mm min	102±6mm	
8.5	280mm min	108±6mm	
9	280mm min	114±6mm	
9.5	280mm min	121±6mm	

The compliance level is an AQL of 4.0.

4.2 Strength

The force at break of the gloves (median of 13 gloves) is not less than 9.0N.

4.3 Watertightness

The gloves are so designed and manufactured that they have adequate watertightness and are free from holes to function as a barrier against microorganism transmission. The compliance level is an AQL of 0.65.

4.4 Residue powder content： ≤ 2.0mg/glove

4.5 Leachable proteins： ≤200μg/g

4.5 Sterility

The gloves are provided pre-sterilized, using ionizing radiation to acheive a SAL of 10^{-6}.

The periodc documented validation of the effectiveness of the sterilization method and audit of the appropriateness of the established radiation dose is conducted in accordance with ISO 11137-1 and -2 to ensure the sterilization activity is reliable and reproducible.

5. Types

Where their finish is concerned, the gloves are divided into two types, smooth and textured. The former is smooth all over, whereas the latter has a textured area covering the palm and the front part of the thumb and fingers.

In terms of how the cuff is formed, the gloves also have two types, cuffed and uncuffed. A cuffed glove has a rolled rim at the cuff, and an uncuffed one does not.

6. Packaging:

The gloves, with their wrists turned inside out, are placed in pairs into paper wrappers, which are then packaged in paper or poly pouches. After being sealed by the sealing machine, the pouches are put into boxes, which are then packed into outer cartons prior to sterilization.

The effectiveness of the sealing process is periodically validated in accordance to ISO 11607-2 to ensure that sterile barrier system integrity is attained in a reliable and reproducible manner.

7. Shelf life:

The Mumu Natural Rubber Surgical Gloves have a claimed shelf life of 3 years at 25℃ based on the accelerated aging study data.

8. Biocompatibility

The Mumu Natural Rubber Surgical Gloves have undergone various relevant biological tests, including skin irritation test, sensitization test, *in vitro* cytotoxicity test, material mediated pyrogenicity test, acute systemic toxicity test, and heamolysis test, in accordance with ISO 10993 series. The data generated from the tests collectively support the conclusion that the gloves have good biocompatibility and are safe to both users and patients when used according to their intended application.

9. Instruction for use:

- Please use before the expiry date as indicated by package labeling.
- Select the right size that best suits your hands.
- For easy donning, dry your hands if they are wet.
- Avoid any sharp or barbed objects to prevent puncture or cut in the gloves. Trim your fingernails if necessary.

- If the gloves are found broken during use, discard them and use a new pair after hand disinfection.
- Replace the gloves with a new pair if they have been in use for more than 4 hours to prevent the risk of glove damage from increasing.
- Do not expose this product to intense light, such as sunlight or ultraviolet ray.
- Avoid contact with oils, acids, alkalis, or other chemicals that can have damaging effects on rubber.

10. Warning:

- This product contains natural rubber latex which may cause allergic reactions.
- Do NOT use if the sterile package is damaged or unintentionally opened before use.
- This product is disposable and for single use only. Reuse of this product may increase the risk of contamination.
- Dispose of this product as medical waste after use, since the used gloves may be contaminated with potentially infectious substance of human origin.

11. Storage conditions:

Store in a cool, dry, and well-ventilated environment free of any corrosive gases. Shield open boxes from direct sun and fluorescent lighting.

12. Notice:

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Compiled by: (Name/signature)		Position:	QA Manager
Reviewed by (Name/signature)		Position:	Deputy G.M.
Approved by: (Name/signature)		Position:	Management Rep.

Publication Date: October 9, 2024
Revision Date: November 29, 2024

GUILIN HBM HEALTH PROTECTIONS, INC.

EC DECLARATION OF CONFORMITY

REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: /	Guilin HBM Health Protections, Inc. No.1-2, Shuijing East Road, Economic and Technological Development Area, 541805 Guilin, Guangxi, China
EC Authorized Representative:/	HBM Medical Coliemore House, Coliemore Roud, Dalkey, Co Dublin, A96 A8D5, Ireland

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and their transpositions into national laws which apply to the device. All supporting documentations are retained under the premises of this manufacturer.

Name of the medical device: /	Medispo® Essential Natural Rubber Latex Surgical Gloves
Model: /	Powder-free Textured Cuffed Natural Rubber Powder-free Textured Uncuffed Natural Rubber Powder-free Smooth Cuffed Natural Rubber Powder-free Smooth Uncuffed Natural Rubber
Specification:	5.5, 6, 6.5, 7,7.5, 8, 8.5 ,9, 9.5.
UMDNS Code:/	11883
Basic UDI-DI:/	697178707SGNRUF
Intended purpose: /	The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.
Classification/	Rule 7, Class Ⅱa, according to annex VIII of directive EU 2017/745(MDR) / CND code: T01010102, SURGICAL GLOVES, LATEX, NON-POWDERED
Conformity assessment: /	Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /
Notified Body: /	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands CE 2797
Registration No.: /	

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

Place & Date　　Name & Title

Guilin HBM Health Protections, Inc.
Oct. 8th , 2024

Signature:
QMR

Product Name: Natural Rubber Latex Surgical Gloves

Applicable standards lists

（Harmonized standards,international standards,partly applicable standards)

Relevant standards applied to the device are listed as follows:

Table 1 Compliance Standards for Natural Rubber Latex Surgical Gloves

No.	Standards	Reference	Content
1.	Regulation (EU) 2017/745	2017	Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	MEDDEV2.7.1	Rev4	Clinical Evaluation : A guide for manufacturers and notified bodies under directives
3.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
4.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
5.	MDCG 2020-6	2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
6.	MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template
7.	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)
8.	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices

9.	ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
10.	ISO 10993-4	2017	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
11.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity(ISO 10993-5:2009)
12.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
13.	EN ISO 10993-11	2017,	Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
14.	EN 62366-1	2015	Medical devices — Part 1: Application of usability engineering to medical devices
15.	EN ISO 13485	2016	Medical devices-Quality management systems- Requirements for regulatory purpose
16.	EN 455-1	2020	Medical gloves for single use -Part 1: Requirements and testing for freedom from holes
17.	EN 455-2	2015	Medical gloves for single use Part 2: Requirements and testing for physical properties
18.	EN 455-3	2015	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
19.	EN 455-4	2009	Medical gloves for single use Part 4: Requirements and testing for shelf life determination
20.	ISO 11607-1	2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
21.	ISO 11607-2	2019	Validation requirements for forming, sealing and assembly processes

22.	ISO 11737-1	2018	Sterilization of medical devices —Microbiological methods —Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
23.	ISO 11737-2	2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
24.	EN ISO 11137-1	2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
25.	ISO 11137-2	2017	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
26.	ISO 11137-3	2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
27.	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness
28.	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
29.	EN 868-1	1997	Packaging materials and systems for medical devices which are to be sterilized - Part 1:General requirements and test methods
30.	EN 868-5	2018	Packaging materials and systems for medical devices which are to be sterilized - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

EC DECLARATION OF CONFORMITY

REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: /	Guilin HBM Health Protections, Inc. No.1-2, Shuijing East Road, Economic and Technological Development Area, 541805 Guilin, Guangxi, China
EC Authorized Representative:/	HBM Medical Coliemore House, Coliemore Roud, Dalkey, Co Dublin, A96 A8D5, Ireland

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and their transpositions into national laws which apply to the device. All supporting documentations are retained under the premises of this manufacturer.

Name of the medical device: /	Medispo® Premium Polyisoprene Surgical Gloves
Model: /	Powder-free Textured Cuffed Polyisoprene Rubber Powder-free Textured Uncuffed Polyisoprene Rubber Powder-free Smooth Cuffed Polyisoprene Rubber Powder-free Smooth Uncuffed Polyisoprene Rubber
Color:	Cream, brown, green, blue
Size:	5.5, 6, 6.5, 7,7.5, 8, 8.5 ,9, 9.5.
UMDNS Code:/	11883
Basic UDI-DI:/	697178707SGPIU3
Intended purpose：/	The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.
Classification/	Rule 7, Class Ⅱa, according to annex VIII of directive EU 2017/745(MDR) / CND code: T01010203 SURGICAL GLOVES, POLYISOPRENE
Conformity assessment: /	Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /
Notified Body: /	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands CE 2797
Registration No.: /	MDR 747912 R000

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

Place & Date	Name & Title
Guilin HBM Health Protections, Inc. Oct. 8th, 2024	Signature: _____, QMR

GUILIN HBM HEALTH PROTECTIONS, INC.

Lists of Applicable Regulation and Standards

(Harmonized standards, international standards, partly applicable standards)

Relevant standards applied to the device are listed as follows:

No.	Standards	Reference	Content
1.	MDR (EU) 2017/745	2017	Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	MEDDEV2.7.1	Rev4	Clinical Evaluation : A guide for manufacturers and notified bodies under directives
3.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
4.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
5.	MDCG 2020-6	2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
6.	MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template
7.	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
8.	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
9.	ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
10.	ISO 10993-4	2017	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
11.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

12.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
13.	EN ISO 10993-11	2017	Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
14.	EN 62366-1	2015	Medical devices — Part 1: Application of usability engineering to medical devices
15.	EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purpose
16.	EN 455-1	2020	Medical gloves for single use -Part 1: Requirements and testing for freedom from holes
17.	EN 455-2	2015	Medical gloves for single use Part 2: Requirements and testing for physical properties
18.	EN 455-3	2015	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
19.	EN 455-4	2009	Medical gloves for single use Part 4: Requirements and testing for shelf life determination
20.	ISO 11607-1	2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
21.	ISO 11607-2	2019	Validation requirements for forming, sealing and assembly processes
22.	ISO 11737-1	2018	Sterilization of medical devices —Microbiological methods —Part 1: Determination of a population of microorganisms on products
23.	ISO 11737-2	2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
24.	EN ISO 11137-1	2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
25.	ISO 11137-2	2015	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
26.	ISO 11137-3	2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
27.	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness
28.	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
29.	EN 868-1	1997	Packaging materials and systems for medical devices which are to be sterilized - Part 1:General

			requirements and test methods
30.	EN 868-5	2018	Packaging materials and systems for medical devices which are to be sterilized - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

EC DECLARATION OF CONFORMITY

REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: /	Guilin HBM Health Protections, Inc. No.1-2, Shuijing East Road, Economic and Technological Development Area, 541805 Guilin, Guangxi, China
EC Authorized Representative:/	HBM Medical Coliemore House, Coliemore Roud, Dalkey, Co Dublin, A96 A8D5, Ireland

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and their transpositions into national laws which apply to the device. All supporting documentations are retained under the premises of this manufacturer.

Name of the medical device: /	Medispo® Premium Natural Rubber Latex Surgical Gloves
Model: /	Powder-free Textured Cuffed Natural Rubber Powder-free Textured Uncuffed Natural Rubber Powder-free Smooth Cuffed Natural Rubber Powder-free Smooth Uncuffed Natural Rubber
Specification:	5.5, 6, 6.5, 7,7.5, 8, 8.5 ,9, 9.5.
UMDNS Code:/	11883
Basic UDI-DI:/	697178707SGNRUF
Intended purpose: /	The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.
Classification/	Rule 7, Class Ⅱa, according to annex VIII of directive EU 2017/745(MDR) / CND code: T01010102, SURGICAL GLOVES, LATEX, NON-POWDERED
Conformity assessment: /	Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /
Notified Body: /	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands CE 2797
Registration No.: /	

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

Place & Date　　Name & Title

Guilin HBM Health Protections, Inc.
Oct. 8th , 2024

Signature:
QMR

Product Name: Natural Rubber Latex Surgical Gloves

Applicable standards lists

（Harmonized standards,international standards,partly applicable standards)

Relevant standards applied to the device are listed as follows:

Table 1 Compliance Standards for Natural Rubber Latex Surgical Gloves

No.	Standards	Reference	Content
1.	Regulation (EU) 2017/745	2017	Regulation(EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
2.	MEDDEV2.7.1	Rev4	Clinical Evaluation : A guide for manufacturers and notified bodies under directives
3.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
4.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
5.	MDCG 2020-6	2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC
6.	MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template
7.	EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)
8.	EN ISO 14971	2019	Medical devices - Application of risk management to medical devices

9.	ISO 10993-1	2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
10.	ISO 10993-4	2017	Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood
11.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity(ISO 10993-5:2009)
12.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
13.	EN ISO 10993-11	2017,	Biocompatibility Evaluation of Medical Device - Part 11: Tests for systemic toxicity
14.	EN 62366-1	2015	Medical devices — Part 1: Application of usability engineering to medical devices
15.	EN ISO 13485	2016	Medical devices-Quality management systems- Requirements for regulatory purpose
16.	EN 455-1	2020	Medical gloves for single use -Part 1: Requirements and testing for freedom from holes
17.	EN 455-2	2015	Medical gloves for single use Part 2: Requirements and testing for physical properties
18.	EN 455-3	2015	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
19.	EN 455-4	2009	Medical gloves for single use Part 4: Requirements and testing for shelf life determination
20.	ISO 11607-1	2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
21.	ISO 11607-2	2019	Validation requirements for forming, sealing and assembly processes

22.	ISO 11737-1	2018	Sterilization of medical devices —Microbiological methods —Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
23.	ISO 11737-2	2020	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
24.	EN ISO 11137-1	2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
25.	ISO 11137-2	2017	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose
26.	ISO 11137-3	2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control
27.	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness
28.	EN ISO 14644-2	2015	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)
29.	EN 868-1	1997	Packaging materials and systems for medical devices which are to be sterilized - Part 1:General requirements and test methods
30.	EN 868-5	2018	Packaging materials and systems for medical devices which are to be sterilized - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

EC DECLARATION OF CONFORMITY

REGULATION 2017/745 ON MEDICAL DEVICE

Name and address of the manufacturer: / **Guilin HBM Health Protections, Inc.**

No.1-2, Shuijing East Road, Economic and

Technological Development Area, 541805 Guilin, Guangxi, China

EC Authorized Representative:/ HBM Medical
Coliemore House, Coliemore Roud, Dalkey, Co Dublin,
A96 A8D5, Ireland

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and their transpositions into national laws which apply to the device. All supporting documentations are retained under the premises of this manufacturer.

Name of the medical device	Brand Name	Sizes	Classification
Natural Rubber Latex Surgical Gloves	Medispo	5.5/6.0/6.5/7/7.5/8/8.5/9.0/9.5	Class IIa

UMDNS Code:/ 11883

Basic UDI-DI:/ 697178707SGNRUF

Intended purpose： / The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

Classification/ Rule 7, Class Ⅱa, according to annex VIII of directive EU 2017/745(MDR) /
CND code:
T01010102, SURGICAL GLOVES, LATEX, NON-POWDERED

Conformity assessment: / Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annex IX chapter I and III,Annex IX Chapter II of Regulation (EU) 2017/745,
according to Article 52(7) of Regulation (EU) 2017/745

Notified Body: / BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands
CE 2797

Registration No.: / MDR 747912 R000

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Guilin 30/10/2022
Place, date

Pu Lei
Pu lei/Quality Director Name and Position

EC DECLARATION OF CONFORMITY

REGULATION 2017/745 ON MEDICAL DEVICE

Name and address of the manufacturer: / **Guilin HBM Health Protections, Inc.**

No.1-2, Shuijing East Road, Economic and

Technological Development Area, 541805 Guilin, Guangxi, China

EC Authorized Representative:/ HBM Medical
Coliemore House, Coliemore Roud, Dalkey, Co Dublin,
A96 A8D5, Ireland

As the manufacturer of the following medical device, we herewith declare under our sole responsibility that the stated medical device meets the provisions of Medical Device Regulation of EU 2017/745:2017 and their transpositions into national laws which apply to the device. All supporting documentations are retained under the premises of this manufacturer.

Name of the medical device	Brand Name	Sizes	Classification
Natural Rubber Latex Surgical Gloves	mumu brand	5.5/6.0/6.5/7/7.5/8/8.5/9.0	Class IIa

UMDNS Code:/ 11883

Basic UDI-DI:/ 697178707SGNRUF

Intended purpose：/ The surgical gloves are sterile and single use device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.

Classification/ Rule 7, Class Ⅱa, according to annex VIII of directive EU 2017/745(MDR) /
CND code:
T01010102, SURGICAL GLOVES, LATEX, NON-POWDERED

Conformity assessment: / Declare the conformity of the above mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annex IX chapter I and III,Annex IX Chapter II of Regulation (EU) 2017/745,
according to Article 52(7) of Regulation (EU) 2017/745

Notified Body: / BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands
CE 2797

Registration No.: / MDR 747912 R000

Meets the provisions of the Regulation EU 2017/745(MDR) which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Guilin 30/10/2022
Place, date

Pu Lei
Pu lei/Quality Director Name and Position