

# Medispo<sup>®</sup> Premium







WORLD'S LARGEST PRODUCER: Guilin HBM Health Protections, Inc. is one of the top 3 producers of specialist surgical gloves in the world. Accredited to ISO EN13485 quality management systems we hold CE Mark and 510K approval for EU and USA. We have over 20 years' experience in manufacturing Surgical Gloves and support Healthcare Professionals in over 50 countries worldwide.



**CARE FOR THE ENVIRONMENT:** Located in a pristine natural environment our local government rigorously enforces pollution controls. In response, we have developed innovative solutions to minimizing our impact on the environment.

Our goal is to be carbon neutral by 2030.

- Clean energy at point of use; high-pressure steam and electricity.
- Elimination of all chlorine use in production
- We are working with local government to source energy from renewable methods.
- Our in-house E-Beam steriliser does not have the contaminated radioactive waste problems associated with gamma ray sterilisation.



**CARE FOR OUR COMMUNITY (CSR):** All workers at the factory live locally and we do not employ any immigrant work force. We offer a hygienic and safe work environment with competitive pay to attract workers and build upon our standing in the community.



**EFFICIENCY:** Our production platform uses computerized control combined with Artificial Intelligence predictive quality analytics preventing problems in advance and means our state-of-the-art facility is one of the most efficient in the world.





Each Medispo® Surgical Glove Matters WE CARE FOR EACH GLOVE WE MAKE.



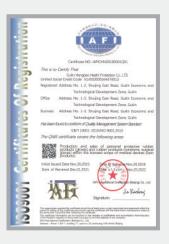
# WORLD LEADING QUALITY ASSURANCE SYSTEMS

- FDA 510K
- CE Mark, Certificate 6048797 CE01, Notified Body DEKRA Certification B.V. 0344
- MDR EU Quality Management System Certificate MDR 747912, Notified Body BSI Group The Netherlands B.V. 2797
- ISO 9001 / ISO 13485 / MDSAP Certified
- ISO 14001, Environmental Management
- ISO 45001, Occupational Health & Safety
- PPE Certificate, Notified Body BSI Group The Netherlands B.V. 2797





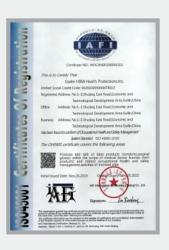










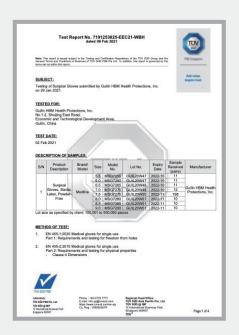




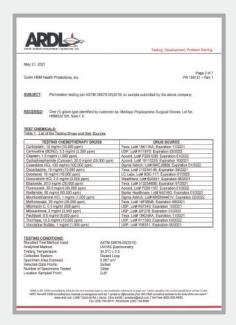


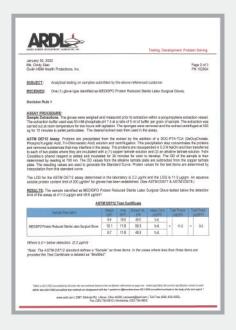
# WORLD CLASS LABORATORY TESTING

- EN455-1/2/3/4 tested by PSB / Singapore
- · Chemo Drug Permeation Test ASTM 6978 by ARDL / USA
- Comparison Physical Property Test we are among world top 5 brands' quality level - by ARDL / USA
- · PPE tested by SATRA
- · Medispo Pristine PND Gloves Protein Non-detectable tested by ARDL / USA
- · AQL way beyond any international standards

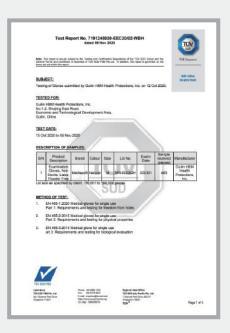














# **POLYISOPRENE**

SURGICAL GLOVES

**Best Performance Non-latex Synthetic** 





## Medispo® PI Features:



Latex-free: Super soft polyisoprene formulation that is also tough to protect you and patients from pathogens. Exceeds all strength requirements according to USA and EU International standards.



**Skin-friendly formulation:** Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



BSI Group The Netherlands B.V. Regulation (EU) 2017/745 BSI Group The Netherlands B.V. Regulation (EU) 2016/425

## **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





ATION
Medispo® Polyisoprene, Sterile, Hand Specific, 280-300mm
Latex-free, Polyisoprene
White Cream
Beaded cuff
ZDEC
Micro textured, calibrated grip, medium
Sterile,E-Beam / Gamma
Powder-free
Anatomical, forward thumb ball, hand specific
0.65
EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
ISO 9001, ISO 13485:2016, ISO 14001
3 Years
EU MDR 2017/745, USA 510k, MDSAP
DEKRA, SATRA, ARDL, BSI
PPE Regulation (EU) 2016/425, Type B
EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION								
Item No.	MPIG-5.5	MPIG-6.0	MPIG-6.5	MPIG-7.0	MPIG-7.5	MPIG-8.0	MPIG-8.5	MPIG-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length <sub>(±5mm)</sub>	280	280	280	285	285	290	290	300
Thickness (±0.03mm)	Fingertip:0.22			Palm:0.19	9		Cuff:0.16	

PACKING INFORMATION					
Pouch material	Long or square plastic peel pouch				
Packing Quantity	Pouch	Inner box	Shipping Carton		
Packing Quantity	1pair/pouch	50pairs/box	200pairs/carton		

EUROPEAN REPRESENTATION						
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382					
EC Rep Contact Details	INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com					





# **POLYISOPRENE**

SURGICAL UNDERGLOVES

**Best Performance Non-latex Synthetic** 





## Medispo® PI Under Features:



**Perforation detection:** Medispo PI Underglove is an ideal underglove when double-gloving. Designed to interlock with Medispo PI overglove to deliver an excellent single glove experience. Our distinct blue colour aids in clearly and quickly alerting wearers to perforations in the outer glove. Designed to be comfortable and reliable for any type of surgical procedure.



**Protection:** Computer control and predictive quality analytics (AI) mean that each glove undergoes rigorous quality controls before release. In addition, each glove is 100% air-leaked and visually inspected.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



## **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





# Medispo POLYISOPRENE UNDER SURGICAL GLOVES

PRODUCT INFORM	ATION
Product Name / Description	Medispo® POLYISOPRENE UNDER , Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Latex-free, Polyisoprene
Color	Blue
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION								
Item No.	MPUG-5.5	MPUG-6.0	MPUG-6.5	MPUG-7.0	MPUG-7.5	MPUG-8.0	MPUG-8.5	MPUG-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length(±5mm)	280	280	280	285	285	290	290	300
Thickness(±0.03mm)	Fingertip: 0.22			Palm:0.1	9		Cuff:0.16	

PACKING INFORMATION					
Pouch material	Long or square plastic peel pouch				
Packing Quantity	Pouch	Inner box	Shipping Carton		
Packing Quantity	1pair/pouch	50pairs/box	200pairs/carton		

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EC Rep & Registration No. HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382

**EC Rep Contact Details** INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com





# **POLYISOPRENE**

SENSITIVE SURGICAL GLOVES

**Designed For Super Sensitive Touch And Comfort** 





## **Medispo® PI Sensitive Features:**



**Sensitive tactility:** Medispo PI Sensitive is designed for surgeons who demand a higher tactile sensitivity.



**Skin-friendly formulation:**Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



## **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577



PRODUCT INFORM	ATION
Product Name / Description	Medispo® POLYISOPRENE Sensitive, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Latex-free, Polyisoprene
Color	White Cream
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION								
Item No.	MPSE-5.5	MPSE-6.0	MPSE-6.5	MPSE-7.0	MPSE-7.5	MPSE-8.0	MPSE-8.5	MPSE-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length(±5mm)	280	280	280	285	285	290	290	300
Thickness (±0.03mm)	Fingertip:0.20			Palm:0.19	9		Cuff:0.15	

PACKING INFORMATION						
Pouch material	Long or square plastic peel pouch					
Packing Quantity	Pouch	Inner box	Shipping Carton			
Packing Quantity	1pair/pouch	50pairs/box	200pairs/carton			

EUROPEAN REPRESENTATION						
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382					
EC Rep Contact Details	INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com					





## **ORTHOPAEDIC**

POLYISOPRENE SURGICAL GLOVES

**Thicker And Stronger For Added Protection** 





## Medispo® PI Orthopaedic Features:



Robust protection: Medispo PI Orthopaedic is our thickest glove in the PI portfolio. Our proprietary mould and microtextured finish delivers comfort with tactile sensitivity. Dark brown colour reduces glare from surgical lighting.



**Skin-friendly formulation:** Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



BSI Group The Netherlands B.V. Regulation (EU) 2017/745 BSI Group The Netherlands B.V. Regulation (EU) 2016/425

## **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





# Medispo PI ORTHOPAEDIC SURGICAL GLOVES

PRODUCT INFORM	ATION
Product Name / Description	Medispo® Polyisoprene Orthopaedic, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Latex-free, Polyisoprene
Color	Dark Brown
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT	SPECIFIC	ATION						
Item No.	MPOG-5.5	MPOG-6.0	MPOG-6.5	MPOG-7.0	MPOG-7.5	MPOG-8.0	MPOG-8.5	MPOG-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length(±5mm)	280	280	280	285	285	290	290	300
Thickness(±0.03mm)	Fingertip: 0.27			Palm:0.2	3		Cuff:0.18	

PACKING INFORMATION				
Pouch material	Long or square plastic peel pouch			
Packing Quantity	Pouch	Inner box	Shipping Carton	
racking Quantity	1pair/pouch	50pairs/box	200pairs/carton	

		<b>TATION</b>

EC Rep & Registration No. HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382

**EC Rep Contact Details** INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com





# **MEDISPO® TPC**

LATEX SURGICAL GLOVES

Powder Free Latex
Our Best Value Product





## **Medispo® TPC Features:**



Comfort, dexterity and protection: Building upon 20 years feedback from our customers HBM have designed a new mould to better fit with clinician's hands. Our new mould offers high-level comfort and dexterity. You may use Medispo TPC as your only glove, or as an overglove when double-gloving with a Medispo Latex Underglove to help protect you and your patients with perforation detection.



**Protection:** Computer control and predictive quality analytics (AI) mean that each glove undergoes rigorous quality controls before release. In addition, each glove is 100% air-leaked and visually inspected.



**Skin-friendly formulation:** Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



BSI Group The Netherlands B.V. Regulation (EU) 2017/745 BSI Group The Netherlands B.V. Regulation (EU) 2016/425

## **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





#### PRODUCT INFORMATION **Product Name / Description** Medispo® TPC, Sterile, Hand Specific, 280-300mm Latex / Latex-free/ material Natural rubber latex White Cream Color Beaded cuff **Cuff type** Accelerators used **ZDEC** Texture / Grip Micro textured, calibrated grip, medium Sterile, E-Beam / Gamma Sterile / Non-Sterile / Method Powder / Powder-free Powder-free Anatomical, forward thumb ball, hand specific Design 0.65 **AQL** value EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, **International Product Standards** ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107 ISO 9001, ISO 13485:2016, ISO 14001 Quality/Environmental Standards **Shelf Life** 3 Years EU MDR 2017/745, USA 510k, MDSAP Compliance to regulations DEKRA, SATRA, ARDL, BSI Notified body/Test Laboratories PPE Regulation (EU) 2016/425, Type B PPE compliance / Type **Biological Evaluation** EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test Additional tests Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION								
Item No.	MTPC-5.5	MTPC-6.0	MTPC-6.5	MTPC-7.0	MTPC-7.5	MTPC-8.0	MTPC-8.5	MTPC-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length <sub>(±5mm)</sub>	280	280	280	285	285	290	290	300
Thickness (±0.03mm)	Fingertip:0.22			Palm:0.19			Cuff:0.16	

PACKING INFORMATION				
Pouch material	Long or square plastic peel pouch			
Packing Quantity	Pouch	Inner box	Shipping Carton	
racking Quantity	1pair/pouch	50pairs/box	200pairs/carton	

EUROPEAN REPRESENTATION				
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382			
EC Rep Contact Details	INFO@4SHBM.COM. Telephone +353 1 582 2308 www.4shbm.com			





# UNDERGLOVE

LATEX SURGICAL GLOVES

**Easy-don Colored Undergloves Perforation Detection System** 





## **Medispo® Latex Underglove Features:**



**Perforation detection:** Medispo TPC Underglove is an ideal underglove when double-gloving. Designed to interlock with Medispo TPC overglove to deliver an excellent single glove experience. Our distinct green colour aids in alerting wearers to perforations in the outer glove. Designed to be comfortable and reliable for any type of surgical procedure.



**Protection:**Computer control and predictive quality analytics (AI) mean that each glove undergoes rigorous quality controls before release. In addition, each glove is 100% air-leaked and visually inspected.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



BSI Group The Netherlands B.V. Regulation (EU) 2017/745 BSI Group The Netherlands B.V. Regulation (EU) 2016/425

## **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





PRODUCT INFORM	ATION
Product Name / Description	Medispo® Latex Underglove, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Natural rubber latex
Color	Green
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION									
Item No.	MLUG-5.5	MLUG-6.0	MLUG-6.5	MLUG-7.0	MLUG-7.5	MLUG-8.0	MLUG-8.5	MLUG-9.0	
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#	
Length <sub>(±5mm)</sub>	280	280	280	285	285	290	290	300	
Thickness (±0.03mm)	Fingertip:0.22			Palm:0.19			Cuff:0.16		

PACKING INFORMATION				
Pouch material	Long or square plastic peel pouch			
Packing Quantity	Pouch	Inner box	Shipping Carton	
racking Quantity	1pair/pouch	50pairs/box	200pairs/carton	

EUROPEAN REPRESENTATION				
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382			
EC Rep Contact Details	INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com			





# **SENSITIVE**

**LATEX SURGICAL GLOVES** 

**Designed For Super Sensitive Touch And Comfort** 





## **Medispo<sup>®</sup> Sensitive Features:**



**Sensitive tactility:** Medispo Sensitive is designed for surgeons who prefer a natural rubber latex surgical glove but demand a higher tactile sensitivity.



**Skin-friendly formulation:**Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



### **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





# MEDISPO® SENSITIVE LATEX SURGICAL GLOVES

PRODUCT INFORM	ATION
Product Name / Description	Medispo® Sensitive, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Natural rubber latex
Color	White Cream
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION								
Item No.	MLSG-5.5	MLSG-6.0	MLSG-6.5	MLSG-7.0	MLSG-7.5	MLSG-8.0	MLSG-8.5	MLSG-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length <sub>(±5mm)</sub>	280	280	280	285	285	290	290	300
Thickness (±0.03mm)	Fingertip:0.20			Palm:0.17			Cuff:0.14	

PACKING INFORMATION						
Pouch material	Long or square plastic peel pouch					
Packing Quantity	Pouch	Inner box	Shipping Carton			
racking Quantity	1pair/pouch	50pairs/box	200pairs/carton			

EUROPEAN REPRESENTATION						
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382					
EC Bon Contact Details	INFO@ACUDM.COM. Telephone 1252 4 502 2200 Junio Ashbra 2272					





# ORTHOPAEDIC

**LATEX SURGICAL GLOVES** 

**Thicker And Stronger For Added Protection** 





## **Medispo® Orthopaedic Features:**



**Robust protection:** Medispo Orthopaedic is our thickest glove in the latex portfolio. Our proprietary mould and microtextured finish delivers comfort with tactile sensitivity. Warm brown colour reduces glare from surgical lighting.



**Skin-friendly formulation:** Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



**Easy donning:** Skin friendly polymer coated for easy donning even with damp hands saving you time.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



BSI Group The Netherlands B.V. Regulation (EU) 2017/745 BSI Group The Netherlands B.V. Regulation (EU) 2016/425

### **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





# Medispo ORTHOPAEDIC LATEX SURGICAL GLOVES

PRODUCT INFORM	ATION
Product Name / Description	Medispo® Orthopaedic, Sterile, Hand Specific, 280-300mm
Latex / Latex-free/ material	Natural rubber latex
Color	Brown
Cuff type	Beaded cuff
Accelerators used	ZDEC
Texture / Grip	Micro textured, calibrated grip, medium
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma
Powder / Powder-free	Powder-free
Design	Anatomical, forward thumb ball, hand specific
AQL value	0.65
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001
Shelf Life	3 Years
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue

PRODUCT SPECIFICATION								
Item No.	MLOG-5.5	MLOG-6.0	MLOG-6.5	MLOG-7.0	MLOG-7.5	MLOG-8.0	MLOG-8.5	MLOG-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length <sub>(±5mm)</sub>	280	280	280	285	285	290	290	300
Thickness (±0.03mm)	Fingertip:0.30			Palm:0.27			Cuff:0.20	

PACKING INFORMATION						
Pouch material	Long or square plastic peel pouch					
Packing Quantity	Pouch	Inner box	Shipping Carton			
r acking equalitity	1pair/pouch	50pairs/box	200pairs/carton			

EUROPEAN REPRESENTATION						
EC Rep & Registration No.	HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382					
EC Rep Contact Details	INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com					





# PRISTINE™

LATEX SURGICAL GLOVES

Super-soft, strong and comfortable Ideal companion for Medispo Latex Underglove



## Medispo<sup>®</sup> PRISTINE™ Features:



**Soft and tough:**Medispo-PRISTINE™ is our softest formulation glove, and delivers an enhanced level of comfort and tactility. PRISTINE™'s formulation is also tough with remarkable tensile strength and force at break.



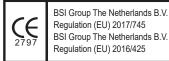
Ideal double-glove companion: Medispo-PRISTINE™ combined with Medispo green under-gloves offer an ideal combination for hole detection in the outer glove. Medispo double gloving system offers world leading protection and optimal comfort levels available. Medispo double gloving system is easy to don yet locks in place and behaves like one glove.



**Skin-friendly formulation:**Our unique chlorine-free formulation production processes combined with the absence of chemical accelerators known to cause allergic responses mean skin irritations are minimised or eliminated. Tested according to ISO EN 10993.



Consistent calibrated grip: The outer surface of Medispo surgical gloves are specially treated to provide a consistent grip. The grip is monitored and controlled during production and each lot must pass stringent internal grip controls before being released.



### **Complies with the following Standards and Regulations:**

Quality: ISO 9001, EN ISO 13485

Compliance EU: CE Mark, MDR, EN 455 1-4, EN ISO 374 1-5

Compliance USA: 510K, ASTM D3577





# Medispo PRISTINETM

## **LATEX SURGICAL GLOVES**

PRODUCT INFORMATION						
Product Name / Description	Medispo® -PRISTINE™, Sterile, Hand Specific, 280-300mm					
Latex / Latex-free/ material	Natural rubber latex					
Color	White Cream					
Cuff type	Beaded cuff					
Accelerators used	ZDEC					
Texture / Grip	Micro textured, calibrated grip, medium					
Sterile / Non-Sterile / Method	Sterile,E-Beam / Gamma					
Powder / Powder-free	Powder-free					
Design	Anatomical, forward thumb ball, hand specific					
AQL value	0.65					
International Product Standards	EN 455 1-4, EN ISO 374 1-5:2016, EN ISO 21420:2019, ASTM D3577, ASTM D6978, ASTM F739, ISO 10993, AS/NZS 4179, ISO 10282, JIS T9107					
Quality/Environmental Standards	ISO 9001, ISO 13485:2016, ISO 14001					
Shelf Life	3 Years					
Compliance to regulations	EU MDR 2017/745, USA 510k, MDSAP					
Notified body/Test Laboratories	DEKRA, SATRA, ARDL, BSI					
PPE compliance / Type	PPE Regulation (EU) 2016/425, Type B					
Biological Evaluation	EN 10993, Primary Skin Irritation Test, Dermal Sensitization Assay, Cytotoxicity Test					
Additional tests	Viral Penetration PPE Compliance (ASTM F1671), Chemotherapy Drugs (ASTM D6978), Chemical Residue					

PRODUCT SPECIFICATION								
Item No.	MPND-5.5	MPND-6.0	MPND-6.5	MPND-7.0	MPND-7.5	MPND-8.0	MPND-8.5	MPND-9.0
Size	5.5#	6.0#	6.5#	7.0#	7.5#	8.0#	8.5#	9.0#
Length <sub>(±5mm)</sub>	280	280	280	285	285	290	290	300
Thickness (±0.03mm)	Fingertip:0.19			Palm:0.17			Cuff:0.14	

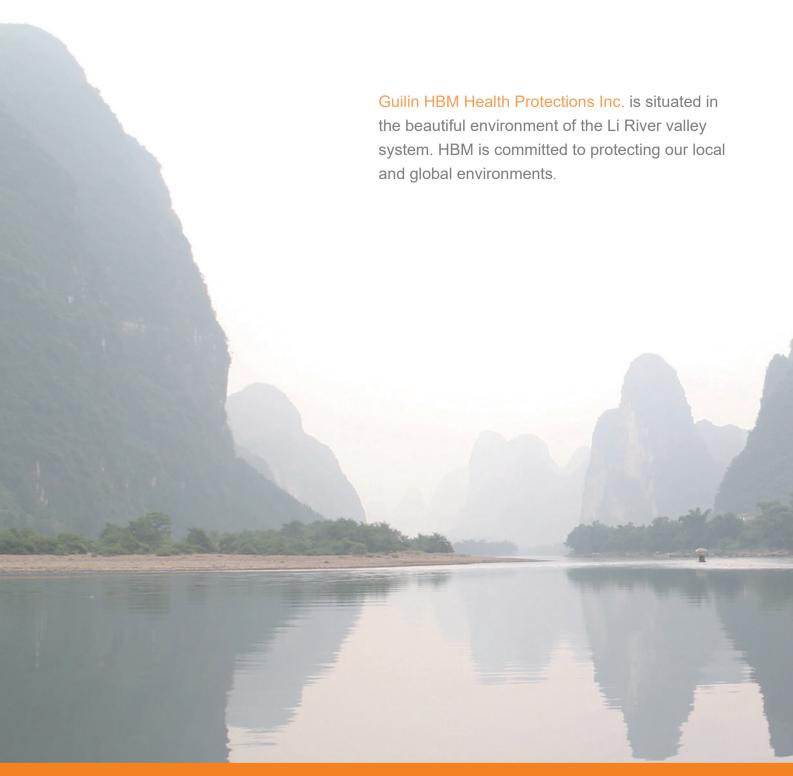
PACKING INFORMATION						
Pouch material	Long or square plastic peel pouch					
Packing Quantity	Pouch	Pouch Inner box				
Facking Quantity	1pair/pouch	50pairs/box	200pairs/carton			

## **EUROPEAN REPRESENTATION**

EC Rep & Registration No. HBM Medical, Coliemore House, 3 Coliemore Road, Dalkey, Co Dublin, Ireland: 653382

**EC Rep Contact Details** INFO@4SHBM.COM, Telephone +353 1 582 2308, www.4shbm.com







## Factory Address

#### **Guilin HBM Health Protections, Inc.**

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- www.hbmchina.com

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- info@4shbm.com
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## US office

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