



DOC. TITLE: Declaration of Conformity MDR Sterile Powder-Free Surgical Gloves			
DOCUMENT NO:	RE00199053	REVISION:	2

DECLARATION OF CONFORMITY	
 <p>We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.</p>	
Declaration of Conformity Number	RE00199053
Technical Documentation Number	<ul style="list-style-type: none"> • RE00191989 Protexis™ Latex Sterile Powder-Free Surgical Gloves with Nitrile Coatings • RE00191990 (Old STED Number)/ RE00238844 (New STED Number) Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating • RE00191984 Sterile Latex Powder-Free Surgical Gloves with Neu-Thera Coating • RE00191987 (Old STED Number)/ RE00239959 (New STED Number) Protexis™ Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating • RE00191988 Protexis™ Sterile Polyisoprene Powder-Free Surgical Gloves with No Coating • RE00190828 (Old STED Number)/ RE00232310 (New STED Number) Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating • RE00191991 Sterile Polyisoprene Powder-Free Surgical Gloves with Neu-Thera Coating
Manufacturer's Name	Cardinal Health 200, LLC also trading as Cardinal Health
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Single Registration Number	US-MF-000006765
Authorized Representative's Name and Address	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
Notified body's Name and Identification Number	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Identification Number: 2797
CE Certificate Number	MDR 784266
Product Category	Sterile, Powder-Free Surgical Gloves
Basic UDI-DI	Refer to Attachment 1
EMDN	Refer to Attachment 1

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Product Code, Trade Name and Description	Refer to Attachment 1
Intended Purpose	Surgical gloves are disposable sterile devices intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. In addition, Surgical gloves are intended to provide protection to the wearer against hazardous chemicals.
Classification and Rule	Class: IIa Rule: 7
Common Specifications	Not Applicable
Where appropriate, add applicable Union legislation	We, Cardinal Health 200 LLC, hereby declare the above listed Medical Device(s) complies with: Regulation (EU) 2016/425 for personal protective equipment
Conformity Assessment	Annex IX Chapter I and Chapter III

SIGNATURE SECTION	
This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.	
Place of Issue	Waukegan, IL 60085 USA
Signature/ Date	 <i>Electronically signed by: Deb Kipp</i> <i>Reason: Approved</i> <i>Date: Feb 5, 2025 09:39 CST</i>
Name and Function	Feb 5, 2025 Deb Kipp, Manager - Regulatory Affairs

ATTACHMENT 1

Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D72LU55	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 5.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LU60	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 6.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D72LU65	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 6.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LU70	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 7.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LU75	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 7.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LU80	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 8.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LU85	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 8.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LU90	Protexis™ Latex Blue with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 9.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP55	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 5.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP60	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 6.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP65	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 6.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP70	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 7.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D73TP75	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 7.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP80	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 8.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP85	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 8.5	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D73TP90	Protexis™ Latex with Neu-Thera™, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings, Size 9.0	06301400000000000005186Y	T01010102	Class IIa, Rule 7
2D72LS55	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 5.5	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LS60	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LS65	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.5	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LS70	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LS75	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.5	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LS80	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LS85	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with	06301400000000000005206K	T01010102	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Hydrogel Coating, Size 8.5			
2D72LS90	Protexis™ Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 9.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT60	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT65	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.5	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT70	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT75	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.5	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT80	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT85	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.5	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72LT90	Protexis™ Latex Ortho Surgical Gloves, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating, Size 9.0	06301400000000000005206K	T01010102	Class IIa, Rule 7
2D72NT55X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 5.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NT60X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NT65X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.5	063014000000000000051972	T01010102	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D72NT70X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NT75X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NT80X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NT85X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NT90X	Protexis™ Latex Micro, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 9.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N55X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 5.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N60X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N65X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N70X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N75X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N80X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N85X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72N90X	Protexis™ Latex Classic, Sterile Latex Powder-Free Surgical Gloves with	063014000000000000051972	T01010102	Class IIa, Rule 7

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Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Nitrile Coating, Size 9.0			
2D72NS55X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 5.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS60X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS65X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS70X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS75X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS80X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS85X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72NS90X	Protexis™ Latex, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 9.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE55	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 5.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE60	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE65	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 6.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE70	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.0	063014000000000000051972	T01010102	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D72LE75	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 7.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE80	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE85	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 8.5	063014000000000000051972	T01010102	Class IIa, Rule 7
2D72LE90	Protexis™ Latex Essential, Sterile Latex Powder-Free Surgical Gloves with Nitrile Coating, Size 9.0	063014000000000000051972	T01010102	Class IIa, Rule 7
2D73PM55	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 5.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM60	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 6.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM65	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 6.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM70	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 7.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM75	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 7.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM80	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 8.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM85	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 8.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73PM90	Protexis™ PI Micro, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 9.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL55X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 5.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL60X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical	06301400000000000005176W	T01010203	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Gloves, Size 6.0			
2D72PL65X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 6.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL70X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 7.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL75X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 7.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL80X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 8.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL85X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 8.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PL90X	Protexis™ PI Classic, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 9.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT55X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 5.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT60X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 6.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT65X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 6.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT70X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 7.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT75X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 7.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT80X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 8.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D72PT85X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 8.5	06301400000000000005176W	T01010203	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D72PT90X	Protexis™ PI, Sterile Polyisoprene Powder- Free Surgical Gloves, Size 9.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET60	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 6.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET65	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 6.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET70	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 7.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET75	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 7.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET80	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 8.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET85	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 8.5	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73ET90	Protexis™ PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves, Size 9.0	06301400000000000005176W	T01010203	Class IIa, Rule 7
2D73TE55	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 5.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73TE60	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 6.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73TE65	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 6.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73TE70	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 7.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73TE75	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient	06301400000000000005156S	T01010203	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Coating, Size 7.5			
2D73TE80	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 8.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73TE85	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 8.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73TE90	Protexis™ PI with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 9.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB55	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 5.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB60	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 6.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB65	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 6.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB70	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 7.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB75	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 7.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB80	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 8.0	06301400000000000005156S	T01010203	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D73EB85	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 8.5	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D73EB90	Protexis™ PI Blue with Neu-Thera™, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating, Size 9.0	06301400000000000005156S	T01010203	Class IIa, Rule 7
2D72TG55	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 5.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG60	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG65	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG70	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG75	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG80	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG85	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D72TG90	Protexis™ PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 9.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73HT60	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating,	06301400000000000005146Q	T01010203	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Size 6.0			
2D73HT65	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 6.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73HT70	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73HT75	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 7.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73HT80	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73HT85	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 8.5	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73HT90	Protexis™ PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating, Size 9.0	06301400000000000005146Q	T01010203	Class IIa, Rule 7
2D73DS55	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 5.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DS60	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 6.0	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DS65	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 6.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DS70	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile	06301400000000000005126L	T01010201	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
	Coating, Size 7.0			
2D73DS75	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 7.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DS80	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 8.0	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DS85	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 8.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DS90	Protexis™ Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 9.0	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP55	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 5.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP60	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 6.0	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP65	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 6.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP70	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 7.0	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP75	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 7.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP80	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 8.0	06301400000000000005126L	T01010201	Class IIa, Rule 7

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Product Code List				
Product Code	Trade Name and Description	Basic UDI-DI	EMDN	Classification and Rule
2D73DP85	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 8.5	06301400000000000005126L	T01010201	Class IIa, Rule 7
2D73DP90	Protexis™ Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating, Size 9.0	06301400000000000005126L	T01010201	Class IIa, Rule 7






RE00199053

Final Audit Report

2025-02-05

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