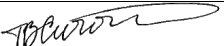


DECLARATION OF CONFORMITY

MDD: We, Cardinal Health 200 LLC, declare that the products covered in this Declaration of Conformity meet the provision of the Council Directive 93/42/EEC for Medical Devices as amended by 2007/47/EC and as transposed in the national laws of the Member States.

Technical Documentation Number	DC001
Manufacturer's Name	Cardinal Health 200, LLC also trading as Cardinal Health
Manufacturer's Address	3651 Birchwood Drive Waukegan, IL 60085 USA
Authorized Representative's Name and Address	Emergo Prinsessegracht 20, 2514 AP, The Hague, The Netherlands
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	553828
Product Name	Sterile Surgical Gloves, see table provided in Attachment 1.
Basic UDI-DI	This information is not applicable for MDD technical documentation. Not Applicable (N/A).
Product Code(s) and Description	See the Product Code List table provided in Attachment 1
Intended Purpose	A sterile surgeon's glove is a disposable medical device made of natural rubber latex or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. Various thickness for sensitivity or durability depending on need.
Classification and Rule	Class IIa (Annex II, Rule 7)
Single Registration Number	This information is not applicable for MDD technical documentation. Not Applicable (N/A).
Common Specifications	Not Applicable (N/A)
Other applicable Union legislation	We, Cardinal Health, herewith, declare that the devices listed also comply with the requirements of the Regulation (EU) 2016/425 for personal protective equipment.
Conformity assessment	Annex II (excluding Section 4) of MDD 93/42/EEC Council Directive, Class IIa, Rule 7; See Attachment 1 for further details.
GMDN Code	Please reference Attachment 1

SIGNATURE SECTION			
This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.			
Place of Issue	3651 Birchwood Drive Waukegan, IL 60085 USA		
Signature		Date	Mar 6, 2020
Title/Position	Director, Regulatory Affairs		

ATTACHMENT 1

DECLARATION OF CONFORMITY				
Product Code	GMDN	Product Description	Classification and Rule	Basic UDI-DI
2D7200I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7201I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7202I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7203I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7204I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7205I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7206I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7207I	47179	Triflex Custom Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7255LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7260LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7265LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7270LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7275LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7280LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7285LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7290LP	47179	Triflex LP, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7250IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7251IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7252IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7253IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7254IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7255IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7256IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D7257IF	47179	Triflex, Sterile Latex Powdered Surgical Gloves	Class IIa, Rule 7	Not applicable
2D72LU55	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU60	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU65	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU70	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU75	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU80	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU85	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LU90	47178	Protexis Latex Blue with Neu-Thera, Sterile Latex Powder-Free Surgical Gloves with Nitrile and Emollient Coatings	Class IIa, Rule 7	Not applicable
2D72LS55	47178	Protexis Latex Hydrogel, Sterile Latex Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable

DECLARATION OF CONFORMITY

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DECLARATION OF CONFORMITY

Product Code	GMDN	Product Description	Classification and Rule	Basic UDI-DI
2D73EB90	56293	Protexis PI Blue with Neu-Thera, Sterile Polyisoprene Powder-Free Surgical Gloves with Emollient Coating	Class IIa, Rule 7	Not applicable
2D73ET60	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D73ET65	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D73ET70	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D73ET75	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D73ET80	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D73ET85	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D73ET90	56293	Protexis PI Ortho, Sterile Polyisoprene Powder-Free Surgical Gloves	Class IIa, Rule 7	Not applicable
2D72TG55	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG60	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG65	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG70	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG75	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG80	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG85	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D72TG90	56293	Protexis PI Textured, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT60	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT65	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT70	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT75	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT80	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT85	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73HT90	56293	Protexis PI Orthopaedic, Sterile Polyisoprene Powder-Free Surgical Gloves with Hydrogel Coating	Class IIa, Rule 7	Not applicable
2D73DS55	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS60	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS65	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS70	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS75	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS80	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS85	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DS90	57970	Protexis Neoprene Essential, Sterile Synthetic Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable

DECLARATION OF CONFORMITY

Product Code	GMDN	Product Description	Classification and Rule	Basic UDI-DI
2D73DP55	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP60	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP65	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP70	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP75	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP80	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP85	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable
2D73DP90	57970	Protexis Neoprene, Sterile Neoprene Powder-Free Surgical Gloves with Nitrile Coating	Class IIa, Rule 7	Not applicable

(EU) Declaration of Conformity (MDD)_DC001_Rev.57_Surgical Gloves

Final Audit Report

2020-03-06

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Status:	Signed
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