

Declaration of Conformity – DC001

PRODUCT IDENTIFICATION		
Scope of Application	Model/number	GMDN Codes
Sterile Surgical Gloves	See attached reference list	See attached list

LEGAL MANUFACTURER	
Name of company	Address
Cardinal Health 200, LLC also trading as Cardinal Health	1500 Waukegan Rd Waukegan, IL 60085 USA

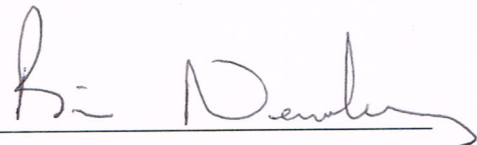
EU AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION		
Notified Body and ID #	CE certificate number	First Issued (Place/Date)
BSI 0086 Kitemark Court Davy Avenue, Knowhill Milton Keynes, MK5 8PP	CE 553828	London, October 7, 2009

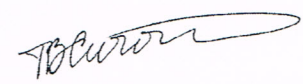
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 7	Annex II.3 of MDD 93/42/EEC Council Directive	EN ISO 13485:2016 Medical Devices – Quality Management Systems

Cardinal Health declares that the above mentioned products 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.

QUALITY MANAGEMENT REPRESENTATIVE: Brian Newbery, Director

SIGNATURE:  DATE: 10/MAY/18

REGULATORY AFFAIRS MANAGEMENT REPRESENTATIVE: Tatyana Bogdan, Director

SIGNATURE:  DATE: May 9, 2018