



EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 798506 R000

Manufacturer: Cardinal Health 200, LLC

Address:

3651 Birchwood Drive
Waukegan
Illinois
60085
USA

Single Registration Number: US-MF-000006765

EU Authorised Representative: Cardinal Health Ireland Manufacturing Limited

Address:

Tullamore Business & Technology Park
Tullamore
County Offaly
R35 H903
Ireland

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-02-21**

Current Issue Date: **2024-02-21**

Starting Validity Date: **2024-02-21**

Expiry Date: **2029-02-20**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Needles	Class Is
Syringes	Class Is
Tubular devices	Class Is
Adapters, connectors, ramps, stopcocks, caps	Class Is
Nutrition and infusion bags and containers, single use	Class Is
Gastrointestinal tubes and sets	Class Is
Gauzes	Class Is
Special Dressing	Class Is
Magnetic Drape	Class Is
Operating room accessories	Class Is
Pneumology instruments for removal of secretions	Class Is
Skin cleansing wipes	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3833425	Issued



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