



## 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 Global Regulatory & Quality

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

Current Issue Date: **2025-11-24**

Starting Validity Date: **2025-11-24**

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

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

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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
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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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.

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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
2024-02-21	3833425	Issued
Current	30495144	Amended – Change in critical subcontractor for manufacturing and sterilization of fluid management tubing and Kangaroo pediatric gravity feeding set. Restricted – Removal of device group Magnetic drape and all associated devices within the group. Restricted – Removal of Monoject Blunt Cannulas no longer placed on the market.

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