

# 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

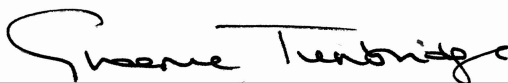
**Address:**

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](mailto:Certificate.Verification@bsigroup.com))

| Date    | Reference Number | Action |
|---------|------------------|--------|
| Current | 3833425          | Issued |

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