EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 784266 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 IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: **2024-02-27**

Current Issue Date: **2024-05-07**

Starting Validity Date: **2024-05-07**

Expiry Date: **2029-02-26**

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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Sterile Polyurethane Dressing	Intended to act as a primary or secondary layer in wound dressings, to serve as a barrier between the skin and/or wound and the environment, and to absorb exudate.

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

Device(s)	Risk Classification
Enteral Feeding Pump	Class IIa
Sterile and Non-Sterile Enteral Feeding Pump Tubing Sets	Class IIa
Sterile and non-sterile Nasogastric Tubes	Class IIa

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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
2024-02-27	3833425	Issued
Current	30122257	Amended - Change to the intended purpose of the Sterile Polyurethane dressing to align with TD. Specification on sterility status to align with device schedule. Supplemented - Addition of sterile nasogastric tubes devices to the MDR device schedule.

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