By Royal Charter

EU Quality Assurance Certificate

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

MDR 768587 R000

Manufacturer: Medline International France SAS

Address:
5, rue Charles Lindbergh
Chateaubriant
44110
France

Single Registration Number: FR-MF-000000676

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: **2023-05-10**

Current Issue Date: **2023-11-28**

Starting Validity Date: **2023-11-28**

Expiry Date: **2028-05-09**

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

Device(s)	Risk Classification
Wound Protector Drape	Class IIa
Surgical Gowns	Class Is
Surgical Drapes, Drape packs and accessories	Class Is
Equipment and Instrument Covers	Class Is
Plastic Bone Cement Mixing with Spatulas	Class Is
Plastic Cautery Holsters	Class Is
Patient Plastic Devices and sets (Cups and lids, bowls and lids, basins and lids, trays and pitchers)	Class Is
Table Cover	Class Is
Surgical Skin Marker and Ruler	Class Is
Suction tubing and accessories	Class Is
Instrument Pad	Class Is
Securement Dressing	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
2023-05-10	3655293	Issued
Current	30050666	Amended: Addition of subcontract manufacturer and sterilization service provider for Class Is Securement Dressing Amended: Removal of sterilization service provider for surgical drapes and gown packs Supplemented: Addition of Class Is Securement Dressing

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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.

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