

EU Quality Assurance Certificate

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

MDR 768587 R000

Manufacturer: Medline International France SAS

Address:

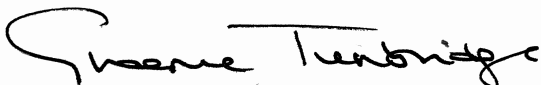
5, rue Charles Lindbergh
Chateaubriant
44110
France

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 Global Regulatory & Quality

First Issue Date: **2023-05-10**

Current Issue Date: **2024-07-03**

Starting Validity Date: **2024-07-03**

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
Suture Boots	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
2023-11-28	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
2024-04-04	30124632	Supplemented - Addition of Class IIa Suture Boots device Amended - Addition of subcontractor manufacturing location for Class Is surgical drapes, gowns and drape packs
Current	30209651	Amended - Addition of ethylene oxide sterilization subcontractor

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