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 Global Regulatory & Quality

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

Current Issue Date: **2025-12-03**

Starting Validity Date: **2025-12-03**

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

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

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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
2024-07-03	30209651	Amended - Addition of ethylene oxide sterilization subcontractor
2024-08-05	30231542	Amended - Addition of subcontractor manufacturing location Amended - Minor address update to sterilization subcontractor, no change of location
2024-11-25	30264388	Supplemented - Addition of Class Is Isolation Gowns
2025-04-21	30358298	Amended - Addition of EtO sterilization subcontractor for surgical procedure drapes, equipment covers, drape packs and accessories for drapes and gowns and addition of a manufacturing & EtO sterilization subcontractor for surgical procedure drapes, surgical gowns, surgical drape packs.
2025-07-15	30490722	Amended - Update to EtO sterilization subcontractor address following move.

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Date	Reference Number	Action
Current	30592091	Amended - Addition of manufacturing and EtO sterilization subcontractor for surgical gowns.

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