EU Quality Assurance Certificate

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

MDR 768667 R000

Manufacturer: Medline International France SAS

Address:
5, rue Charles Lindbergh
Chateaubriant
44110
France

Single Registration Number: FR-PR-000003713

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 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: **2023-05-09**

Current Issue Date: **2025-04-17**

Starting Validity Date: **2025-04-17**

Expiry Date: **2028-05-08**

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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 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Article 22.3 Systems and Procedure Packs

Device(s)		Highest Risk Classification within the System or Procedure Pack
(1)	Angiography Procedure Packs	Class III
(2)	Anaesthesia Procedure Packs	Class III
(3)	Cardiovascular Procedure Packs	Class III
(4)	Chemotherapy Procedure Packs	Class IIb
(5)	Dressing Kits	Class IIa
(6)	Ear, Nose and Throat (ENT) Procedure Packs	Class III
(7)	Endoscopy Procedure Packs	Class III
(8)	General Surgery Procedure Packs	Class III
(9)	Gynaecology Procedure Packs	Class III
(10)	IV Procedure Packs	Class III
(11)	Laparotomy Procedure Packs	Class III
(12)	Maternity Procedure Packs	Class III
(13)	Miscellaneous Medical Procedure Packs	Class IIa
(14)	Neurology Procedure Packs	Class III
(15)	Nursing Dressing Sets	Class III
(16)	Obstetrics/Gynaecology Procedure Packs	Class III
(17)	Ophthalmology Procedure Packs	Class III
(18)	Orthopaedic Procedure Packs	Class III
(19)	Skin Preparation Set	Class IIa
(20)	Stomatology Procedure Packs	Class III
(21)	Bariatric Surgery Procedure Packs	Class IIb
(22)	Biopsy Procedure Packs	Class IIa
(23)	Gastrointestinal Procedure Packs	Class III
(24)	Plastic Surgery Procedure Packs	Class III
(25)	Pressure Monitoring Procedure Packs	Class III
(26)	Proctology Procedure Packs	Class IIb
(27)	Suture Procedure Packs	Class IIb
(28)	Urinary Catheterization Procedure Packs	Class III
(29)	Urology Procedure Packs	Class III

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Device(s)		Highest Risk Classification within the System or Procedure Pack
(30)	Implantology Procedure Packs	Class IIa
(31)	Rhythmology Procedure Packs	Class III
(32)	Paediatric Procedure Packs	Class IIb
(33)	Oral Care Sets	Class IIa
(34)	Probe Cover Kits	Class IIa
For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.		

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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
2023-05-09	3655293	Issued
2024-07-03	30209654	Amended - Addition of ethylene oxide sterilization subcontractor
Current	30288801	Supplemented – updated to highest risk classification of the following devices: Pressure Monitoring Procedure Packs to Class III Urinary Catheterization Procedure Packs to Class III Paediatric Procedure Packs to Class IIb Oral Care Sets to Class IIa Restricted – removal of the following devices: Diagnostics Procedure Packs Dialysis Procedure Packs Microsurgery Procedure Packs IVT Procedure Packs Personal Care sets

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