EU Quality Assurance Certificate

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

MDR 740876 R000

Manufacturer: Medline Industries, LP

Address:
Three Lakes Drive
Northfield
Illinois
60093
USA

Single Registration Number: US-MF-000009717

EU Authorised Representative: Medline International France SAS

Address:
5, rue Charles Lindbergh
Châteaubriant
44110
France

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: **2023-05-04**

Current Issue Date: **2025-01-23**

Starting Validity Date: **2025-01-23**

Expiry Date: **2028-05-03**

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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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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
Pre-filled humidification systems	Class IIa
Aerosol Heaters	Class IIa
Respiratory Masks & Mouthpieces	Class IIa
Nasal Cannulas	Class IIa
Oxygen Administration Tubing	Class IIa
Inhalation therapy humidification liquids	Class IIa
Tracheostomy Adaptors	Class IIa
Respiratory Circuits adaptors, connectors, valves and Respiratory Breathing Circuits	Class IIa
X-Ray Gauze / Laparotomy Sponge	Class IIa
Wound Drain	Class IIa
Natural rubber latex powder free surgical gloves	Class IIa
Synthetic powder free surgical gloves	Class IIa
Disposable Blood Pressure Transducers	Class IIa
Pressure Monitoring Lines including adaptors	Class IIa
Fluid Administration Accessories (torque devices, Y adaptors, Tri Adaptors)	Class IIa
Stopcocks and manifolds	Class IIa
Fluid Delivery Sets	Class IIa
Contrast Injection Lines	Class IIa
Contrast Management Systems	Class IIa
Closed Systems	Class IIa
Angiographic & Radiology Syringes	Class IIa
Saline Flush & Sterile Field Flush and Sterile Luer Access Valve Cap sets	Class IIa

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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
Gauzes, Non woven gauzes	Class Is
Non adhesive absorbent dressings	Class Is
Bulb syringe	Class Is
Suction Tubing and connectors	Class Is
Powder Free Examination Gloves	Class Is
Incentive Spirometers	Class Im
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

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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
2023-05-04	3338327	Issued
2023-05-24	30000495	Supplemented: Addition of device group pre-filled humidification systems Supplemented: Addition of device group Respiratory Masks & Mouthpieces Supplemented: Addition of device group Nasal Cannulas Supplemented: Addition of device group Oxygen Administration Tubing Supplemented: Addition of device group Inhalation therapy humidification liquids Supplemented: Addition of device group Tracheostomy Adaptors Supplemented: Addition of device group Respiratory Circuits adapters, connectors and valves
2024-07-10	30192295	Amended: Update to Class Is examination gloves to clarify powder-free Supplemented: Addition of device group X-Ray Gauze / Laparotomy Sponge Supplemented: Addition of device group Wound Drain Supplemented: Addition of device group Surgical Gloves (powder free natural rubber latex and powder free synthetic) Restricted: Removal of Skin Barrier Film device no longer placed on the market

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Date	Reference Number	Action
2024-10-30	30267926	Supplemented – addition of respiratory breathing circuits; disposable blood pressure transducers; pressure monitoring lines; fluid administration accessories; stopcocks and manifolds; contract injection lines and management systems; closed systems; angiographic & radiology syringes; saline flushes and luer access valve cap sets
Current	30318233	Supplemented – addition of Aerosol Heaters Amended – change in subcontract manufacturing location for natural rubber latex powder free surgical gloves

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