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 Medical Devices

First Issue Date: **2023-05-04**

Current Issue Date: **2023-05-24**

Starting Validity Date: **2023-05-24**

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

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

Device(s)	Risk Classification
Pre-filled humidification systems	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 adapters, connectors & valves	Class IIa
Gauzes, Non woven gauzes	Class Is
Non adhesive absorbent dressings	Class Is
Bulb syringe	Class Is
Suction Tubing and connectors	Class Is
Examination Gloves	Class Is
Skin barrier Film	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
Current	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

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