



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

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





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

### MDR 740876 R000

### **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,	Class Is
Non woven gauzes	
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
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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.

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

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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
2023-05-04	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	

First Issue Date: 2023-05-04 Starting Validity Date: 2023-05-24

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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. A Member of the BSI Group of Companies.