EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 790793 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 IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: **2025-05-20**

Current Issue Date: **2025-05-20**

Starting Validity Date: **2025-05-20**

Expiry Date: **2030-05-19**

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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: Class III and Class IIb devices

Class IIb under Rule 12 – Administer and/or remove a medicinal substance	**Intended purpose**
Pre-filled Large Volume Nebulizer	Intended to add sterile water or saline solution in aerosol form to a patient's breathing gases.
Non-Prefilled Large Volume Nebulizer	Intended to add humidity in aerosol form to respiratory gases delivered to the patient.

Class IIb	**Intended purpose**
Small Volume Nebulizer	Intended to be used for intermittent aerosol therapy to deliver prescribed solutions for inhalation.
Lubricating Jelly	Aplicare Sterile Lubricating Jelly is a sterile lubricant, which can be used to aid the insertion of a catheter.

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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
Current	30423469	Issued

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