EU Quality Management System Certificate ES26/00001179

The management system of

# Medical Respiratory Devices, S.L.

Parque Científico, Avda. de las Américas 4, Nave A7, 28823 Coslada, Madrid, Spain
SRN Number: ES-MF-000000824

has been assessed and certified as meeting the requirements of

## MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 05 November 2026 until 27 January 2031 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 27 July 2030

Issue 2. Organization certified since 28 January 2026 and first certified by SGS on 08 October 2026.

Authorised by
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EU Quality Management System Certificate ES26/00001179, continued

# Medical Respiratory Devices, S.L.

## MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa devices: MDN1202

NEUMOFILT® Ergo bacterial and viral filter for pulmonary function testing equipment, consisting of two ultrasonically welded plastic cases with filtration media housed between them and one case forming the mouthpiece.

Model 1: NEUMOFILT® Ergo [Basic UDI-DI: 843655723NEUMOFILT3G]
Model 2: NEUMOFILT® Ergo Pack Confort [Basic UDI-DI: 843655723NEUMOFILTPCRR]
Model 3: NEUMOFILT® Ergo Pack Plus [Basic UDI-DI: 843655723NEUMOFILTPPSK]
Model 4: NEUMOFILT® Ergo Pack Confort Plus [Basic UDI-DI: 843655723NEUMOFILTPCPVQ]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - ES/MAD/190478 - CTC
Authorized representative name and address (if relevant):
Previous certificate number: 255/MDR
Change in between this certificate and previous one: Update basic UDI-DI mistake for Model 2: NEUMOFILT® Ergo Pack Confort

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