EU Quality Management System Certificate

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

MDR 739877 R000

Manufacturer: Breas Medical Ltd

Address:
Units A1-A2
The Bridge Business Centre
Timothy's Bridge Road
Stratford Enterprise Park
Stratford-upon-Avon
CV37 9HW
United Kingdom

Single Registration Number: GB-MF-000003511

EU Authorised Representative: Breas Medical AB

Address:
Företagsvägen 1
SE-435 33 Mölnlycke
Sweden

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: **2022-06-29**

Current Issue Date: **2025-06-09**

Starting Validity Date: **2025-06-09**

Expiry Date: **2027-06-28**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Airway clearance device	The airway clearance device assists patients in loosening, mobilizing, and clearing secretions, as well as promoting lung volume recruitment by Mechanical Insufflation-Exsufflation (MI-E). The device can be used by adult or paediatric patients that have compromised secretion clearance and/or a reduced ability to cough effectively. The device can be used for MI-E in both invasively and non-invasively ventilated patients as well as patients who are self-ventilating. The device may be used either with a facemask, mouthpiece, or with a suitable adapter to a patient's endotracheal (ET) or tracheostomy tube (MI-E only). The device is intended for use within a hospital, institutional environment, or in the home.

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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
2022-06-29	3328984	Issued
Current	30450277	Amended – Change of device name "Clearway 2" to device group "Airway clearance device".

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