By Royal Charter

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 and Class IIb implantable devices an 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 Medical Devices

First Issued: **2022-06-29** Date: **2022-06-29** Expiry Date: **2027-06-28**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Clearway 2	The Clearway 2 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
Current	3328984	Issued

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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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