

# 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

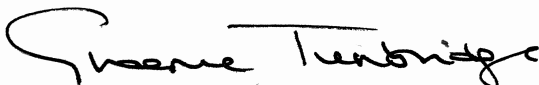
**Address:**

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

Airway clearance device

### Intended purpose

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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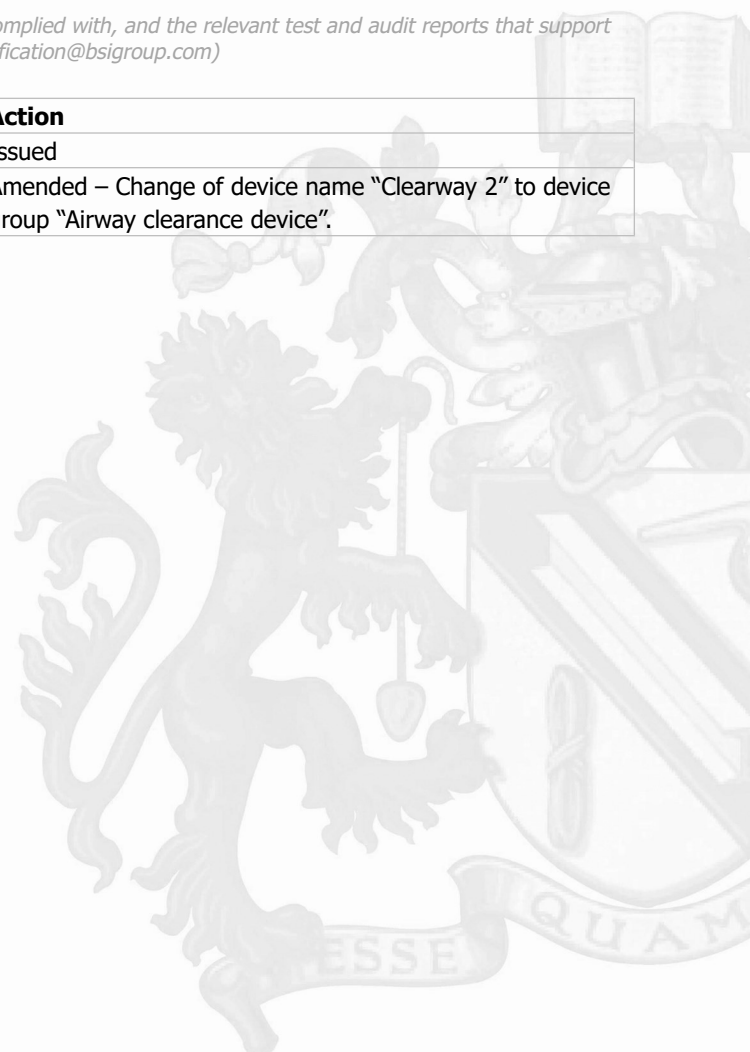
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## Certificate History

*(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](mailto: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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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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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.