

# EU Quality Management System Certificate

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

## MDR 722402 R000

**Manufacturer:** Ambu A/S

**Address:**

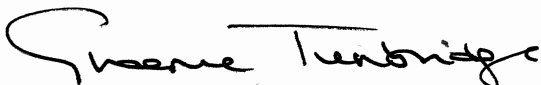
Baltorpbakken 13  
Ballerup  
DK-2750  
Denmark

**Single Registration Number:** DK-MF-000001437

**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 Issue Date: **2021-01-08**

Current Issue Date: **2022-12-07**

Starting Validity Date: **2022-12-07**

Expiry Date: **2026-01-07**

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### Device Schedule: Class III and Class IIb devices

| Class IIb               | Intended purpose   |
|-------------------------|--|
| Neurophysiology devices | Electromyography (EMG) Needle Electrode designed for Botulinum Toxin therapy during nerve block procedures. For single use only. |

### Device Schedule: Class IIa and other devices

| Device(s)   | Risk Classification |
|---|---------------------|
| Endoscopic and Minimally Invasive Surgery Devices                                   | Class IIa           |
| Active Intubation Devices (Endotracheal tubes; Endobronchial tubes)                 | Class IIa           |
| Non-Active Respiratory and Anaesthesia Devices                                      | Class IIa           |
| Neurophysiology devices   | Class IIa           |
| Endoscopic and Minimally Invasive Surgery Devices                                   | Class Is            |
| Non-Active Respiratory and Anaesthesia Devices (Ambu Disposable Pressure Manometer) | Class Im            |

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

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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   |
|------------|------------------|--|
| 2021-01-08 | 3119153          | Issued.  |
| 2021-08-17 | 3487639          | Supplemented – Addition of categories “Intubation Devices” and “Endoscopy Instruments”.<br>Amended - “Endoscopy Instruments” category replaces list of devices. Addition of Ambu Innovation GmbH and SASSE Elektronik GmbH as critical subcontractors.   |
| 2022-01-28 | 3599042          | Supplemented – Addition of “Consumables” to class Is category of “Endoscopy Instruments”.  |
| 2022-03-31 | 3659158          | Amended – Device categories updated to respective EMDN codes/descriptions. Addition of BriteMED as critical subcontractor.   |
| 2022-07-22 | 3716153          | Supplemented - addition of ‘Endobronchial tubes’ and ‘Neurophysiology Devices’ categories. At last issue a typographical error in EMDN meant that ‘Endotracheal tubes’ was added to the certificate scope rather than ‘Endobronchial tubes’. Both tube types are now included on the certificate. Addition of Electron Beam Sdn. Bhd. as critical subcontractor.   |
| 2022-10-28 | 3776296          | Supplemented - Addition of “Non-Active Respiratory and Anaesthesia Devices (Pulmonary resuscitators; Laryngeal Masks)” category in Device Schedule.<br>Amended - Removal of the restrictive wordings within brackets for “Endoscopic and Minimally Invasive Surgery Devices” categories. Removal of EMDN codes in Device Schedule. Combination of “Endotracheal tubes” and “Endobronchial tubes” into one category. Removal of the critical subcontractors/crucial supplies page from certificate. |

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| Date    | Reference Number | Action  |
|---------|------------------|---|
| Current | 3776296          | Supplemented - Addition of class IIb group "Neurophysiology Devices".<br>Amended - Removal of the restrictive wordings within brackets for "Non-Active Respiratory and Anaesthesia Devices" category. |



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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.