By Royal Charter

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**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 722402 R000

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.

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

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

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

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

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 722402 R000

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". 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. 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.

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

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

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

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

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 722402 R000

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

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

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

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

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

...making excellence a habit.™