

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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-01-08**

Date: **2021-08-17**

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

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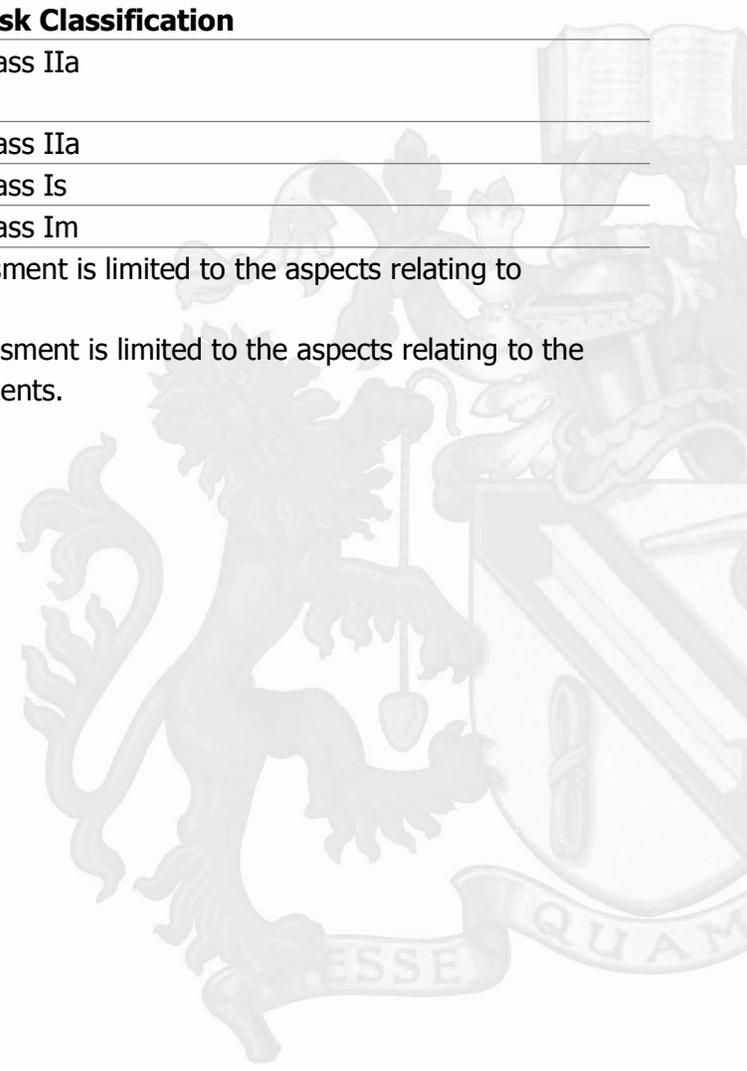
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Device Schedule: Class IIa and other devices

Device(s)	Risk Classification
Endoscopy Instruments (ENT; Pulmonary; Upper Gastrointestinal Tract; Videoprocessors)	Class IIa
Intubation Devices (Endotracheal tubes)	Class IIa
Endoscopy Instruments (Genitourinary)	Class Is
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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Date	Reference Number	Action
2021-01-08	3119153	Issued
Current	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.

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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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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 722402 R000

Date: **2021-08-17**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Ambu Innovation GmbH Karl-Drais-Straße 4B Augsburg 86159 Germany	Design
Ambu Limited No. C Warehouse & Process Complex Building Xiang Yu F.T.Z. Xiamen Fujian Province 361006 P.R. China	Design Manufacture
Ambu Sdn. Bhd. (Company No: 336938-A) Lot 69-B, Lintang Bayan Lepas 6 Phase IV, 11900 Penang Malaysia	Design Manufacture
SASSE Elektronik GmbH Berliner Strasse 12 Schwabach 91126 Germany	Manufacture
SINA-SterilGamma Sdn. Bhd. LOT 88077, Jalan Perigi Nenas 7/1 Taman Perindustrian Pulau Indah 42907 Pelabuhan Klang. Selangor Malaysia	ETO Sterilization

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

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Date: **2021-08-17**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
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Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	ETO Sterilization
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