

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 68734
Issued To: **Ambu A/S**
Baltorpbakken 13
Ballerup
DK-2750
Denmark

In respect of:

The design and manufacture of face masks for ventilators and anaesthesia systems, sterile and non-sterile airway management devices, PEEP valves, manual resuscitators, sterile needle electrodes, sterile disposable endoscopes for airways management. Those aspects of Annex II related to metrology in the design and manufacture of the ventilation upper airway pressure gauges. Those aspects of Annex II related to securing and maintaining sterility in the manufacture of sterile endoscopes for cystoscopy.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2002-07-30**

Date: **2020-10-28**

Expiry Date: **2022-07-28**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 68734

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Number	Device Name	Intended purpose per IFU
Class IIa		
NBOG MD 0101	Airway Management, Resuscitators, Facemasks, Valves, Laryngeal Masks	N/A
NBOG MD 1103	Needle Electrodes	N/A
NBOG MD 1202	Sterile Disposable Endoscopes	N/A
Class I sterile		
NBOG MD 1202	Disposable Endoscopes for Cytoscopy	N/A
Class I measuring		
NBOG MD 0104	Disposable Pressure Manometer	N/A

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