

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Ambu A/S  
Baltorpbakken 13  
Ballerup  
DK-2750  
Denmark

Holds Certificate Number:

**MD 98281**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development and manufacture of PEEP valves; suction devices; manual resuscitators and face masks;  
ventilation upper airway pressure gauges; intubation devices; sterile and non-sterile airway management devices;  
extrication collars; disposable sterile and non-sterile electrodes and EEG, EMG and ECG cables. Sterile disposable endoscopes and endoscope monitor units; clip connector for ECG electrodes. Sterile IVD Sample Container.  
Design and manufacture of abrasive pads.

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2005-07-11

Latest Revision Date: 2021-06-15

Effective Date: 2021-06-19

Expiry Date: 2024-06-18

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Certificate No: **MD 98281**

Location	Registered Activities
Ambu A/S Baltorpbakken 13 Ballerup DK-2750 Denmark	Design, development and manufacture of PEEP valves; suction devices; manual resuscitators and face masks; ventilation upper airway pressure gauges; intubation devices; sterile and non-sterile airway management devices; extrication collars; disposable sterile and non-sterile electrodes and EEG, EMG and ECG cables. Sterile disposable endoscopes and endoscope monitor units; clip connector for ECG electrodes. Sterile IVD Sample Container. Design and manufacture of abrasive pads.
Ambu Innovation GmbH Peterhofstraße 3B Kissing 86438 Germany	The design and development of disposable sterile gastrointestinal endoscopes and monitor units.



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Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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