



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

The Danish Chamber of Commerce do hereby confirm that the company is known to us and registered with the relevant Danish authorities.

Pia Lind
18 JUL 2017

Danish Chamber of Commerce
Secretary: Pia Lind

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 and for cystoscopy.

Those aspects of Annex II related to metrology in the design and manufacture of the ventilation upper airway pressure gauges.

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 0086):

Stewart Brain

Stewart Brain, Head of Compliance & Risk - Medical Devices



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

Date: **2017-05-30**

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.

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Land: Danmark
Country: Denmark
Dette offentlige dokument / This public document
2. er underskrevet af / has been signed by
Pia Lind
3. i egenskab af / acting in the capacity of
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4. er forsynet med segl/stempel af / bears the seal/stamp of
Dansk Erhverv / Danish Chamber of Commerce

Attesteret / Certified

5. i København
at Copenhagen
6. den 18. juli 2017
the 18 July 2017
7. af Udenrigsministeriet
by the Ministry of Foreign Affairs of Denmark
8. Nr. / N° **DNK-00572484**
9. Segl/stempel / Seal/stamp:
10. Underskrift / Signature:


Lotte Greve



ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI ĐAN MẠCH
EMBASSY OF THE S.R OF VIET NAM IN DENMARK

CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia
Country

VIỆT NAM
Viet Nam

Giấy tờ, tài liệu này
This public document

Ký

LOTTE GREVE
LOTTE GREVE

2. do Ông (Bà)
has been signed by

3. với chức danh
acting in the capacity of

4. và con dấu của BỘ NGOẠI GIAO ĐAN MẠCH
bears the seal/stamp of the Ministry of Foreign Affairs of Denmark

Cán bộ hành chính
Administrative Officer

được chứng nhận/hợp pháp hóa lãnh sự
Certified

5. tại COPENHAGEN
at Copenhagen

6. ngày 19/07/2017
19 July 2017

7. Cơ quan cấp ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM
TAI ĐAN MẠCH

by Embassy of the S.R. of Viet Nam in Denmark

8. Số: 78.07/CNLS/17 No: 78.07/CNLS/17

TL. Đại sứ/ For the Ambassador
Bí thư thứ ba/Third Secretary

