

EC Declaration of Conformity

No.: REG-000038

Product Name: Ambu® BlueSensor

REF and Configuration

M-00-Y/NN	SP-00-Y/NN
N-00-Y/NN	T-00-Y/NN
P-00-Y/NN	N-XX-Y/NN
Q-00-Y/NN	Q-XX-Y/NN
R-00-Y/NN	QR-XX-Y/NN

00 states without leadwire.

XX states the lead wire length in cm: 10, 50, 80, 100cm

Accessory: N/A

Identification: All products manufactured after issue date.

We the manufacturer hereby declare that this product is in conformity with the requirements in:

Council directive 93/42/EEC, Annex VII enforced in Danish law.
Equipment class: I, non-sterile according to Annex IX, rule 1

For and on behalf of Ambu A/S, Denmark

22 Apr 2015

Laila Strange Lundtoft, Director, Corporate Regulatory Affairs

First Issued: 28 May 1998

EC Declaration of Conformity – Annex I: GMDN Code

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Product Name: Ambu® BlueSensor

The Ambu® BlueSensor is covered by the following GMDN Code:

GMDN Code: 35035

Term: Electrocardiographic electrode, single-use