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CVR. nr. 63644919

EC Declaration of Conformity No.: REG-000140

Product Name: **Ambu® MARK IV Resuscitator**
Ambu® MARK IV Baby Resuscitator

REF and Configuration

Ambu® MARK IV Resuscitator	304 00x 000, 304003000JA
Ambu® MARK IV Baby Resuscitator	299 00x 000

Operator-powered Resuscitator, reusable

Accessory:

A000 137 000 Ambu® Reusable PEEP 10 valve, A000 213 000 Ambu® Reusable PEEP 20 valve
209 000 508 Oxygen supply tube, 230 000 001 Ambu Pack,
32x xx0 000 Ambu® Laryngeal Masks
000 31x 000 Ambu® Silicone Face Masks; 000 315 000 ONLY FOR MARKIV BABY
A000 01x 000 Ambu® Transparent Face Masks; A000 015 000 ONLY FOR MARK IV BABY
000 251 00x Ambu® Open Cuff Silicone Face Masks; 000 251 001 and 000 251 002 ONLY FOR MARK IV BABY
000 252 95x Ambu® Disposable Face Masks with check valve; 000 252 951 and 000 252 952 ONLY FOR MARK IV BABY
000 252 05x Ambu® Disposable Face Masks / 000 252 051 and 000 252 052 ONLY FOR MARK IV BABY
219 x00 2xx Ambu Emergency Case;
Only Mark IV Resuscitator:
209 000 70x Extension tubes with two adapters, 000 059 274 Adapters for tube, 304 000 507 Oxygen reservoir bag 1500 ml, complete
Only Mark IV Baby Resuscitator:
322 003 000 Ambu® Disposable Pressure Manometer
295 000 504 Patient valve without swivel (only for Japan market)

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 II enforced in Danish law.
Equipment class: IIa, non-sterile, Annex IX rule 2

and in accordance with the authorization given by BSI Certificate No. CE 68734.

For and on behalf of Ambu A/S, Denmark

18 January 2016

Kaja Tengbjerg, Senior Manager Corporate Regulatory Affairs

First Issued: 19 September 2005

EC Declaration of Conformity – Annex I: GMDN Code

No.: REG-000140

Product Name:

Ambu® MARK IV Resuscitator
Ambu® MARK IV Baby Resuscitator

The Ambu® MARK IV Resuscitator & Ambu® MARK IV Baby Resuscitator are covered by the following GMDN Code:

GMDN Code: 17591
Term: Resuscitator, pulmonary, manually-operated, reusable

A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O2) from an O2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device.