

## 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 I and Annex II enforced in Danish law.

Device classification: Class IIa non-sterile, according to Annex IX, rule 2&3

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

**For and on behalf of Ambu A/S, Denmark**

29 March 2019

  
Kaja Tengbjerg, Director, 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