

## 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:** 000 137 000 Ambu® PEEP 10 valve, 000 213 000 Ambu® PEEP 20 valve  
000 171 004 Oxygen supply tube, 230 000 0xx Ambu Packs,  
321 xx0 000 Ambu Laryngeal Masks  
000 31x 000 Ambu® Transparent Silicone Face Masks; 000 315 000 ONLY FOR MARKIV BABY  
01x 001 000 Ambu® Transparent Face Masks; 015 001 000 ONLY FOR MARK IV BABY  
000 251 00x 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 xxx 2xx Ambu Emergency Case; 230 0xx 0xx Ambu Pack; 062 000 055 Ambu Soft Pack  
*Only Mark IV Resuscitator:*  
209 000 70x Extension tubes with two adapters, 000 059 27x Adapters for tube, 304 000 507  
Oxygen reservoir bag 1500 ml, complete  
*Only Mark IV Baby Resuscitator:*  
000 013 000 Ambu® transparent face mask, no. 0A, 000 0xx 000 Rendell-Baker masks, 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**

12 September  
2014

  
Laila Strange Lundtoft, 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**

is covered by the following GMDN Code:

**GMDN Code:** 17591

**Term:** Resuscitator, pulmonary, manually-operated, reusable