

## EC Declaration of Conformity

No.: REG-000139

**Product Name:** Ambu® SPUR® II, Single Patient Use Resuscitator  
Adult, Pediatric and Infant

<b>REF and Configuration</b>	Adult	52x xxx xxx	325 0xx 000
	Pediatric	53x xxx xxx	330 0xx 000
	Infant	54x xxx xxx	335 xxx 000

**Accessory:** Customized items: 325021000RH, 325012000RH, 330004000RH, 330021000RH, 335002000RH, 3350003000RH, 335103000RH  
Customized items: 325002002, 325003002, 325012002, 330006002  
Customized items: 325021000PD, 330021000PD, 335023000PD  
Ambu® Disposable Face masks  
Ambu® PEEP valve  
Ambu® Disposable Pressure Manometer  
Guedel Airway

**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**

3 May 2017

  
Kaja Tengbjerg, Director, Corporate Regulatory Affairs

**First Issued: 29 June 2005**

## **EC Declaration of Conformity – Annex I: GMDN Code**

**No.:** REG-000139

**Product Name:**

Ambu® SPUR® II Single Patient Use Resuscitator Adult, Pediatric and Infant

The Ambu® SPUR® II Single Patient Use Resuscitator Adult, Pediatric and Infant are covered by the following GMDN Code:

**GMDN Code:** 36086

**Term:** Manual pulmonary resuscitator, single patient use

A non-sterile, 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 (O<sub>2</sub>) from an O<sub>2</sub> 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 single-use device