

**B069 EC Declaration of Conformity**

**No.: REG-000050**

**Product Name:** Ambu® Disposable Face Masks

**REF and Configuration** 000252051, 000252052, 000252053, 0002520531, 000252054,  
000252055, 000252056, 000252951, 000252952, 000252953,  
000252954, 000252955, 000252956;  
2K8050, 2K8051, 2K8052, 2K8053, 2K8054, 2K8055,  
65-4417;  
000252051RH, 000252052RH, 000252053RH, 000252054RH,  
000252055RH, 000252056RH, 000252951RH, 000252952RH,  
000252953RH, 000252954RH, 000252955RH, 000252956RH;

**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 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**



13 May 2014

Laila Strange Lundtoft, Senior Manager Corporate Regulatory Affairs

**First Issued: 13 August 1998**

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

**No.: REG-000050**

**Product Name: Ambu® Disposable Face Masks**

The Ambu® Disposable Face Masks are covered by the following GMDN Code:

**GMDN Code:** 46232

**Term:** Anaesthesia face mask, non-scavenging, single-use