

EC Declaration of Conformity

No.: REG-000057

Product Name: Ambu® Silicone Face Masks

REF and configuration
000 314 000
000 316 000
000 312 000
000 317 000
000 319 000
000 315 000
000 313 000

Accessory: N/A

Identification: All products manufactured after issue date

We the manufacturer hereby declare that the stated medical device 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

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

For and on behalf of Ambu A/S, Denmark

26 April 2019


Kaja Tengbjerg, Director, Corporate Regulatory Affairs

First Issued: 1 December 2000

**EC Declaration of Conformity – Annex I: GMDN Code
No.: REG-000057**

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

GMDN code: 17170

Term: Resuscitator face mask, reusable