



AUTHORIZATION LETTER OF EEC REPRESENTATIVE

No.: QA090520001

Date: 2009.05.20

For the following equipment: Open cuff silicone Face masks

REF.:

000 251 001 Size 0 infant

000 251 002 Size 1 infant

000 251 003 Size 2 child

000 251 004 Size 3 child

000 251 005 Size 4 adult/child

000 251 006 Size 5 adult

Is herewith confirmed in accordance with the requirements set out in the Council Directive on the Approximation of the Laws of the Member States relating to requirements of Council Directive 93/42/EEC, Annex II, Section 3.2, Class IIa, under approval by notified body DNV ID No.: 0434 and EC Certificate No.: 38774-2008-CE-NOR.

The following importer is authorized as representative in the EEC to take on regulatory responsibility regarding the products in this declaration.

Name: Ambu A/S

Address: Baltorpbakken 13, DK-2750 Ballerup

Country: Denmark


Manufacturer for this declaration:

Name: GaleMed Corporation

Address: 87, Li-gong 2nd Road, Wu-jia, I-Lan 268

Country: Taiwan, R.O.C.

Countersigned by Ambu International A/S


Laila Strange Lundtoft / Regulatory Affairs Manager


Pin Zeng / Q.A. Engineer

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