

EU Declaration of Conformity

No.: REG-005138

We

Manufacturer: Ambu A/S
Single Registration Number DK-MF-000001437
Postal address: Baltorpbakken 13
City, country: 2750, Ballerup, Denmark
Telephone number: +45 72252000
E-mail address: ambu@ambu.com

declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name Ambu® Disposable Face Mask
Intended purpose The Ambu Disposable Face Mask is a disposable face mask intended for oxygenating and ventilating the airways.

Catalogue number(s) For stand-alone use:

000252051	000252052	000252053	000252054
000252055	000252056	000252951	000252952
000252953	000252954	000252955	000252956
000252053H	000252054H	000252055H	000252056H
000252953H	000252954H	000252955H	000252956H

For use within procedure packs:

000252057	000252058	000252059	000252063
000252064	000252066	000252957	000252958
000252959	000252963	000252961	000252962

Device risk class Class IIa (rule 2, Annex VIII)
Basic UDI-DI 570748030100803208R
GMDN code and term 46232 Anaesthesia face mask, single-use

The devices covered by the present declaration is in conformity with the requirements specified in the relevant Union legislation:

Medical Device Regulation 2017/745

Conformity assessment procedure:

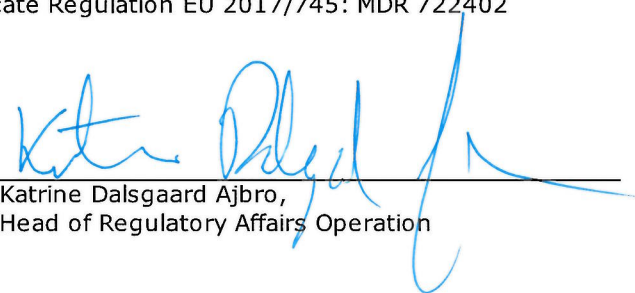
Class IIa: Annex IX - Chapter I and III

Notified body:

BSI
Certificate: EU Quality Management System Certificate Regulation EU 2017/745: MDR 722402
Notified Body number: 2797

Signed for and behalf of Ambu A/S:

Ballerup, Denmark 08-12-2022
[place of issue] [Date of issue]


Katrine Dalsgaard Ajbros,
Head of Regulatory Affairs Operation

First issue: 08-12-2022