

EU Declaration of Conformity

No.: REG-005266

We

Manufacturer: Ambu A/S
Single Registration Number DK-MF-000001437
Postal address: Baltorpbakken 13
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Telephone number: +45 72252000
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declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name Ambu® Silicone Face Mask
Intended purpose The Ambu Silicone Face Mask is a reusable face mask intended for oxygenating and ventilating the airways or to direct anaesthetic gases to the upper airways.

Catalogue number(s) For stand-alone use:
000312000 000313000 000314000 000315000
000316000 000317000 000319000
For use within procedure packs:
000320000 000321000 000322000 000323000
000324000 000326000 000327000

Device risk class Class IIa (rule 2, Annex VIII)
Basic UDI-DI 5707480301008032593
GMDN code and term 17170 Resuscitator face mask, reusable

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

Medical Device Regulation (EU) 2017/745

Conformity assessment procedure:

Class IIa: Annex IX - Chapter I and III

Notified body:

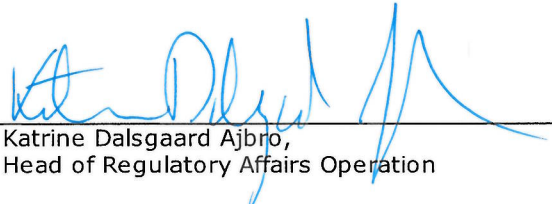
BSI Notified Body number: 2797
Certificate: EU Quality Management System Certificate Regulation EU 2017/745: MDR 722402

Signed for and behalf of Ambu A/S:

Ballerup, Denmark 08-12-2022

[place of issue]

[Date of issue]


Katrine Dalsgaard Ajbrog,
Head of Regulatory Affairs Operation

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