Ambu A/S
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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-005266

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® 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 Ajbro, Head of Regulatory Affairs Operation

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