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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-005597

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® Oval Plus Silicone Resuscitator
Product family	Ambu® Oval Plus Silicone Resuscitator, Reservoir Bag
Intended purpose	The Ambu Oval Plus Silicone Resuscitator is a reusable resuscitator intended for pulmonary resuscitation.
Catalogue numbers	A288201000 370041000 470015100 288011000 370022000 470033000
Device risk class	Class IIa (rule 2, Annex VIII)
Basic UDI-DI	5707480301005500086
GMDN code and term	17591 Manual pulmonary resuscitator, 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	02-11-2022	
Place of issue	Date of issue	Katrine Dalsgaard Ajbro, Head of Regulatory Affairs Operation

First issue: 02-11-2022