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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-005046

We

Manufacturer:	Ambu A/S
Single Registration number	DK-MF-000001437
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City, country:	2750, Ballerup, Denmark
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® AuraOnce™	
Intended purpose	The Ambu AuraOnce is intended for use as an alternative to a facemask for achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in fasted patients.	
Catalogue number(s)	321100000	321100000U
	321150000	321150000U
	321200000	321200000U
	321250000	321250000U
	321300000	321300000U
	321400000	321400000U
	321500000	321500000U
	321600000	321600000U
Device risk class	Class IIa (rule 5, indent 2, Annex VIII)	
Basic UDI-DI	5707480301008001087	
GMDN code and term	45036 Laryngeal mask airway, 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 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	Katrine Dalsgaard Ajbro, Head of Regulatory Affairs Operation
Place of issue	Date of issue	

First issue: 02-11-2022