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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
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® 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 321150000 321200000 321250000 321300000 321400000 321500000 321600000
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	06-02-2023	Katrine Dalsgaard Ajbro, Head of Regulatory Affairs Operation
Place of issue	Date of issue	

First issue: 02-11-2022