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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-005045

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® AuraGain™
Intended purpose	Ambu AuraGain is intended for use as an alternative to a face mask for achieving and maintaining control of the airway during routine and emergency anesthetic procedures.
Catalogue number(s)	408100000 408150000 408200000 408250000 408300000 408400000 408500000 408600000
Device risk class	Class IIa (rule 5, indent 2, Annex VIII)
Basic UDI-DI	570748030100800508K
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