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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-005047

We

Manufacturer:	Ambu A/S
Single Registration number	DK-MF-000001437
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City, country:	2750, Ballerup, Denmark
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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® Aura-i™	
Intended purpose	The Ambu Aura-i is intended for use as an alternative to a face mask for achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in patients evaluated as eligible for a supraglottic airway.	
Catalogue number(s)	329100000	329100000U
	329150000	329150000U
	329200000	329200000U
	329250000	329250000U
	329300000	329300000U
	329400000	329400000U
	329500000	329500000U
	329600000	329600000U
Device risk class	Class IIa (rule 5, indent 2, Annex VIII)	
Basic UDI-DI	570748030100800208A	
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