

## EU Declaration of Conformity

No.: REG-005047

### 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® 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

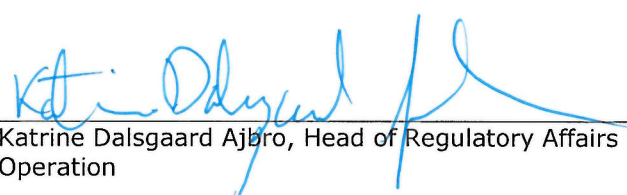
### Notified body:

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  
Place of issue

02-11-2022  
Date of issue

  
Katrine Dalsgaard Ajbø, Head of Regulatory Affairs  
Operation

First issue: 02-11-2022