

## EU Declaration of Conformity

No.: REG-005046

### 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® 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

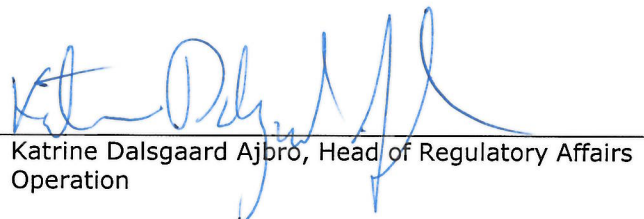
### Notified body:

BSI  
Certificate: EU Quality Management System Certificate Regulation EU 2017/745: MDR 722402  
Notified Body number: 2797

### Signed for and behalf of Ambu A/S:

Ballerup, Denmark  
Place of issue

06-02-2023  
Date of issue

  
Katrine Dalsgaard Ajbro, Head of Regulatory Affairs  
Operation

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