

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

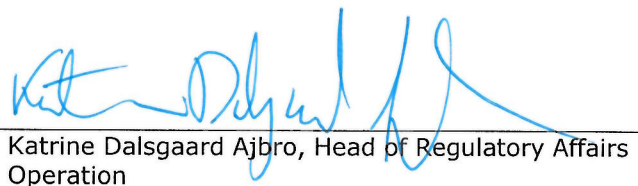
Notified body:

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
Place of issue

02-11-2022
Date of issue


Katrine Dalsgaard Ajbros, Head of Regulatory Affairs
Operation

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