

EU Declaration of Conformity

No.: REG-005271

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® Mark IV
Product family: Ambu® Mark IV, Reservoir Tube
Intended purpose: The Ambu Mark IV is a reusable resuscitator intended for pulmonary resuscitation.
Catalogue number(s): 299011001
299004000
Device risk class: Class IIa (rule 2, Annex VIII)
Basic UDI-DI: 570748030100550508M
GMDN code and term: 17591 Manual pulmonary resuscitator, reusable

The devices covered by the present declaration is in conformity with the requirements specified in the relevant Union legislation:

Medical Device Regulation (EU) 2017/745

Conformity assessment procedure:

Class IIa: Annex IX - Chapter I and III

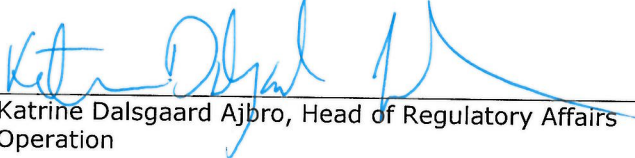
Notified body:

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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