

## EU Declaration of Conformity

No.: REG-005270

### 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 Bag  
Intended purpose: The Ambu Mark IV is a reusable resuscitator intended for pulmonary resuscitation.  
Catalogue number(s): 299011000  
299009000  
304033000  
304004000  
Device risk class: Class IIa (rule 2, Annex VIII)  
Basic UDI-DI: 570748030100550408J  
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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