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CVR. nr. 63644919

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	02-11-2022	
Place of issue	Date of issue	Katrine Dalsgaard Ajbro, Head of Regulatory Affairs Operation

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