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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-004554

We

Manufacturer:	Ambu A/S
Single Registration number	DK-MF-000001437
Postal address:	Baltorpbakken 13
City, country:	2750, Ballerup, Denmark
Telephone number:	+45 72252000
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declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name	Ambu® SPUR® II
Product family	SPUR II Demand Valve Connector Inlet
Intended purpose	The Ambu SPUR II resuscitator is a single patient use resuscitator intended for pulmonary resuscitation
Catalogue number(s)	325207000 330207000 330208000 325208000
Device risk class	Class IIa (rule 2, Annex VIII)
Basic UDI-DI	5707480301005402085
GMDN code and term	36086 Pulmonary resuscitator, manual, 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	07-03-2024	E. Aagaard
Place of issue	Date of issue	Elsebeth Aagaard, Vice President, Regulatory & Clinical Affairs

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