Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark
T +45 72 25 20 00
F +45 72 25 20 50
ambu@ambu.com
www.ambu.com
CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-005044

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® Disposable Pressure Manometer
Intended purpose	The Ambu Disposable Pressure Manometer is intended to be used for monitoring the patient's airway pressure.
Catalogue number(s)	322003000 322007000
Device risk class	Class Im (rule 1, Annex VIII)
Basic UDI-DI	570748030100802008E
GMDN code and term	46634 Airway pressure monitor, non-powered

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 Im: Annex II, Annex III and Annex IX - Chapter I and III (limited to metrology)

Notified body:
BSI Notified Body number: 2797
Certificate: EU Quality Management System Certificate Regulation (EU) 2017/745: MDR 722402

Signed for and on behalf of Ambu A/S:

Ballerup, Denmark	2022-07-29	Kristine Rasmussen, Head of Regulatory Affairs Visualization
Place of issue	Date of issue	

First issue: 2022-07-29