

EU Declaration of Conformity

No.: REG-004725

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® BlueSensor M	Ambu® BlueSensor QR	Ambu® BlueSensor L
	Ambu® BlueSensor P	Ambu® BlueSensor SU	Ambu® BlueSensor R
	Ambu® BlueSensor VLC	Ambu® BlueSensor SP	Ambu® BlueSensor VL
	Ambu® BlueSensor Q	Ambu® BlueSensor N	Ambu® BlueSensor T
Intended purpose	ECG Electrodes		
Catalogue number(s)	M-00-A/50	Q-50-K/25	N-50-A/25
	M-00-F/50	Q-100-K/10	N-10-F/25
	M-00-S/50	QR-50-A/10	N-50-F/25
	P-00-A/50	QR-80-A/10	N-50-K/25
	P-00-F/50	SU-00-A/60	L-00-A/25
	P-00-S/10	SU-00-C/100	L-00-S/25
	P-00-S/12	SU-00-F/60	L-00-S/5
	P-00-S/50	SP-00-A/50	R-00-A/25
	VLC-00-S/4	SP-00-S/4	R-00-S/10
	VLC-00-S/10	SP-00-S/10	R-00-S/25
	VLC-00-S/25	SP-00-S/50	R-00-S/3
	Q-00-A/25	N-00-A/25	R-00-S/4
	Q-00-S/25	N-00-F/25	R-00-S/5
	Q-10-A/25	N-00-S/25	R-00-S/7
	Q-10-F/25	N-10-A/25	VL-00-A/25
Device risk class	Class 1 (rule 1, Annex VIII)		
Basic UDI-DI	5707480301005204587		
GMDN code and term	35035, Electrocardiographic electrode, 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
Restriction of Hazardous Substances Directive (2011/65/EU)

Conformity assessment procedure:


Class I, non-sterile: Annex II and III

Signed for and behalf of Ambu A/S:

Ballerup, Denmark 2021-05-25

Place of issue Date of issue

First issue: 2021-05-25



Kristine Rasmussen, Head of Regulatory Affairs
Innovation, Corporate RA