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CVR. nr. 63644919

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	VL-00-S/10
	M-00-F/50	Q-100-K/10	N-10-F/25	VL-00-S/25
	M-00-S/50	QR-50-A/10	N-50-F/25	VL-10-A/25
	P-00-A/50	QR-80-A/10	N-50-K/25	VL-50-A/25
	P-00-F/50	SU-00-A/60	L-00-A/25	VL-50-K/25
	P-00-S/10	SU-00-C/100	L-00-S/25	T-00-A/25
	P-00-S/12	SU-00-F/60	L-00-S/5	T-00-S/10
	P-00-S/50	SP-00-A/50	R-00-A/25	T-00-S/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),) 2011 as amended by Comission Delegated Directive (EU) 2015/863

Conformity assessment procedure:

Class I, non-sterile: Annex II and III

Signed for and behalf of Ambu A/S:

Ballerup, Denmark

Kaja Tengbjerg

Digitally signed by Kaja Tengbjerg
Date: 2021.07.14 17:19:42 +02'00'

Kaja Tengbjerg, Director, Corporate Regulatory Affairs, Corporate RA

Place of issue

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