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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-004726

We

Manufacturer:	Ambu A/S
Single Registration number	DK-MF-000001437
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City, country:	2750, Ballerup, Denmark
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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 NF		
	Ambu® BlueSensor BR		
	Ambu® BlueSensor BRS		
Intended purpose	ECG Electrodes		
Catalogue number(s)	NF-00-F/12	NF-50-K/W/12	BR-50-A/12
	NF-00-S/12	NF-50-K/W/30	BR-50-K/12
	NF-10-A/12	NF-60-K/W/HC/30	BR-50-K/3
	NF-10-F/12	BR-100-F/C4/4	BR-50-K/EU/12
	NF-10-SC/12	BR-100-F/C6/6	BR-80-A/12
	NF-50-A/12	BR-100-K/12	BR-80-K/12
	NF-50-F/12	BR-100-K/C3/3	BRS-50-A/12
	NF-50-J/3	BR-100-K/C4/4	BRS-50-K/12
	NF-50-J/W/12	BR-100-K/C6/6	BRS-50-K/C3/3
	NF-50-K/12/EU	BR-170-K/C4/4	BRS-50-K/EU/12
	NF-50-K/3/EU	BR-170-K/C6/6	BRS-50-K/EU/3
Device risk class	Class 1 (rule 1, Annex VIII)		
Basic UDI-DI	570748030100520207P		
GMDN code and term	17460, Neonatal Electrocardiograph electrode		

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:

Kaja Tengbjerg

Digitally signed by Kaja Tengbjerg
Date: 2021.07.14 17:20:22 +02'00'

Ballerup, Denmark

Place of issue

Kaja Tengbjerg, Director, Corporate Regulatory Affairs, Corporate RA

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