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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-004736

We

Manufacturer:	Ambu A/S
Single Registration number	DK-MF-000001437
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declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name	Ambu® Neuroline 720
Intended purpose	Neurology Surface Electrodes
Catalogue number(s)	72000-S/25 72001-K/12 72001-SC/12 72010-K/10 72010-K/C/12 72010-M/C/10 72015-J/10 72015-K/10 72015-K/C/12 72020-K/C/12
Device risk class	Class I (rule I, Annex VIII)
Basic UDI-DI	5707480301005203584
GMDN code and term	61020, Analytical non-scalp cutaneous 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)

Conformity assessment procedure:
Class I, non-sterile: Annex II and III

Signed for and behalf of Ambu A/S:

Ballerup, Denmark	2021-05-25	Kristine Rasmussen, Head of Regulatory Affairs Innovation, Corporate RA
Place of issue	Date of issue	

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