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EC DECLARATION OF CONFORMITY

According to Medical Device Regulation (MDR) 2017/745 Annex IV

FECG Legplate

Manufacturer: SRN: Address:	Neoventa Medical AB SE-MF-000001402 Norra Ågatan 32 SE-431 35 Mölndal Sweden

Product names (Article number):	FECG Legplate Adapter for Neoventa (ACC300110) FECG Legplate Adapter for Philips (ACC300120)
Basic UDI-DI:	7340154900018Z
Intended purpose:	The intended purpose of the FECG Legplate is to transfer ECG signals from a fetal spiral electrode (FSE) and a skin electrode to a fetal monitor, for the purpose of monitoring the fetal heart rate or analysis of the fetal ECG waveform.
MDR Device Classification:	Class I, by Rule 1, according to Annex VIII.
Other EU legislation(s) applicable:	Directive 2011/65/EU, including amendments, Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Regulation (EC) No 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Declaration

We, Neoventa Medical AB, are in our role as the manufacturer solely responsible for the conformity of the devices covered by this declaration. We declare that the devices listed in this declaration of conformity meet the provisions of the Medical Device Regulation 2017/745.

Place of issue: Mölndal, Sweden

Date: 2024-11-26

Authorized signatory: Christian Pitulia, CEO