FRESENIUS KABI

EC Declaration of Conformity with article list

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EU DECLARATION OF CONFORMITY

Annex IV of Medical Device Regulation (EU) 2017/745

Product Family Description
Electrode

Product name
Conox Sensor

Article number
Z029061
Z029063

Device classification according to Annex VIII, clause VIII, rule 1
Class I
We

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg, Germany
Single Registration Number (SRN): DE-MF-000009273

manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The products comply with the general safety and performance requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Place and date of issue/	Name (printed letters), position and signature of authorized person/
Brezins, on June 19, 2024	Laurent KELLER Regulatory Affairs Manager

Valid starting with the original date of the document until product change

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CONOX SENSOR

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z029061	CONOX SENSOR	4052682NPM03011xHF0000BL	Z12100302	The Conox Sensor is single-use, three wet-gel electrode arrays applied directly to the patient's skin to allow the collection of physiological signals.	0220314001
Z029063	CONOX PEDIATRIC SENSOR				0221128001