FRESENIUS KABI

EU Declaration of Conformity with article list

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EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10_037258_0012 Rev. 02 and Expiration Date March 09, 2026
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

Product Family Description
Depth of Anaesthesia Monitor

Product name
Conox 2D QM7000-M
Conox 2D

From serial number / Batch number
Refer to attachment

Device classification according to Annex VIII, rule 10 and 11
Class ☑ IIa - IIb

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 declares 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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Attachment to EU DECLARATION OF CONFORMITY

Product Family Description
DEPTH OF ANAESTHESIA MONITOR

Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z029110	CONOX 2D QM7000-M FR	4052682APM03012aCF0000AR	Z12100302	The Conox is intended to monitor patient's consciousness and responsiveness during general anesthesia or sedation.	25532287
Z029120	CONOX 2D QM7000-M DE				25472188
Z029130	CONOX 2D QM7000-M GB				25382142
Z029131	CONOX 2D QM7000-M GB2				25722881
Z029132	CONOX 2D QM7000-M GB3				Not yet manufactured
Z029133	CONOX 2D QM7000-M SA				25592442
Z029140	CONOX 2D QM7000-M BR				25682693
Z029143	CONOX 2D QM7000-M PO				25382144
Z029144	CONOX 2D QM7000-M SK				25803330
Z029145	CONOX 2D QM7000-M HU				25532279
Z029146	CONOX 2D QM7000-M CZ				25472197
Z029148	CONOX 2D QM7000-M RO				25472198
Z029149	CONOX 2D QM7000-M BG				25743051
Z029150	CONOX 2D QM7000-M SE				25472183
Z029153	CONOX 2D QM7000-M HR				25472185
Z029155	CONOX 2D QM7000-M NO				25472182

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Article Number	Product Name	Basic UDI-DI	CND designation	Intended Purpose	From Serial Number
Z029160	CONOX 2D QM7000-M IT				25472201
Z029162	CONOX 2D QM7000-M GR				25472178
Z029170	CONOX 2D QM7000-M NL				25712895
Z029180	CONOX 2D QM7000-M ES				25382157
Z029181	CONOX 2D QM7000-M CL				25472209
Z029182	CONOX 2D QM7000-M ES2				25682812
Z029191	CONOX 2D QM7000-M ZA				25382156
Z029192	CONOX 2D QM7000-M AU				25742922
Z029193	CONOX 2D QM7000-M PL				25562349
Z029195	CONOX 2D QM7000-M KR				25592435
Z029300	CONOX 2D				25953721