



EU DECLARATION OF CONFORMITY

Annex IX, chapter I and III of Regulation 2017/745 according to EC-certificate No. G10
037258 0012 Rev.01 and Expiration Date 2026-03-09
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

Article number
Refer to attachment

From serial number
Z029110 / 25532287
Z029120 / 25472188
Z029130 / 25382142
Z029131 / 25722881
Z029133 / 25592442
Z029140 / 25682693
Z029143 / 25382144
Z029145 / 25532279
Z029146 / 25472197
Z029148 / 25472198
Z029149 / 25743051
Z029150 / 25472183
Z029153 / 25472185
Z029155 / 25472182
Z029160 / 25472201
Z029162 / 25472178
Z029170 / 25712895
Z029180 / 25382157
Z029181 / 25472209
Z029182 / 25682812
Z029191 / 25382156
Z029192 / 25742922
Z029193 / 25562349
Z029195 / 25592435

Device classification according to Annex VIII
Rule 10 and 11, Class IIa

We
Fresenius Kabi AG
61346 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 17-Nov-2023

Heinrich MARTENS
Regulatory Affairs Director

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



Attachment to EU DECLARATION OF CONFORMITY

DEPTH OF ANAESTHESIA MONITOR

Article number	Product name	Basic UDI-DI
Z029110	CONOX 2D QM7000-M FR	4052682APM03012aCF0000AR
Z029120	CONOX 2D QM7000-M DE	
Z029130	CONOX 2D QM7000-M GB	
Z029131	CONOX 2D QM7000-M GB2	
Z029133	CONOX 2D QM7000-M SA	
Z029140	CONOX 2D QM7000-M BR	
Z029143	CONOX 2D QM7000-M PO	
Z029145	CONOX 2D QM7000-M HU	
Z029146	CONOX 2D QM7000-M CZ	
Z029148	CONOX 2D QM7000-M RO	
Z029149	CONOX 2D QM7000-M BG	
Z029150	CONOX 2D QM7000-M SE	
Z029153	CONOX 2D QM7000-M HR	
Z029155	CONOX 2D QM7000-M NO	
Z029160	CONOX 2D QM7000-M IT	
Z029162	CONOX 2D QM7000-M GR	
Z029170	CONOX 2D QM7000-M NL	
Z029180	CONOX 2D QM7000-M ES	
Z029181	CONOX 2D QM7000-M CL	
Z029182	CONOX 2D QM7000-M ES2	
Z029191	CONOX 2D QM7000-M ZA	
Z029192	CONOX 2D QM7000-M AU	
Z029193	CONOX 2D QM7000-M PL	
Z029195	CONOX 2D QM7000-M KR	