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Date: 2021.02.06 12:01:18 EET
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Location: Moldova

EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 047402 0082 and Expiration Date: May 26, 2024
issued by Notified Body TÜV SÜD Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

AmiCORE Apheresis System

Refer to attachment
(Product name)

Refer to attachment
(article number)

Class IIb

We

Fresenius Kabi AG
61346 Bad Homburg, Germany

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 Directive 93/42/EEC, as amended by 2007/47/EC, and its transposition into national laws. The products comply with the essential 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. We hereby declare that the referenced products comply with Directive 2011/65/EU.

Yvonne DeBartolo

Lake Zurich, IL USA 01 Jun 2020 — Yvonne DeBartolo, Sr. Director, Global Strategies and Compliance
Place and date of issue — Name (printed letters), position and signature of authorized person

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

Attachment to EC Declaration of Conformity

AmiCORE Apheresis System

Article Code	Description	GMDN	Physical Manufacturer(s) (name and address)
6R8800	AmiCORE Apheresis System	16405	Plexus Manufacturing Sdn. Bhd. Plot 87, Lebuhraya Kampung Jawa 11900 Bayan Lepas, Penang, Malaysia
			Fresenius HemoCare GmbH Gruener Weg 10, 61169 Friedberg GERMANY