



EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 17 04 47402 052
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123

AmiCORE Apheresis Kits

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.

Lake Zurich, IL, USA

21 Aug 2018

Place and date of issue/

A handwritten signature in blue ink that reads "Yvonne DeBartolo".

Yvonne DeBartolo, Senior Director, Global Strategies and Compliance

Name (printed letters), position and signature of authorized person/

This declaration of conformity is valid for one year from the date of signature



Attachment to EC Declaration of Conformity

AmiCORE Apheresis Kits

Article Number	Product Name	GMDN	Physical Manufacturer (name and address)
C6R8880	AmiCORE Apheresis Kit - Single Needle	47572	1
P6R8880	AmiCORE Apheresis Kit - Single Needle	47572	1
R6R8880	AmiCORE Apheresis Kit - Single Needle	47572	1
X6R8880	AmiCORE Apheresis Kit - Single Needle	47572	1
C6R8882	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers	47572	1
P6R8882	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers	47572	1
R6R8882	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers	47572	1
X6R8882	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers	47572	1
R6R8884	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers; PAS Connector	47572	1
P6R8884	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers; PAS Connector	47572	1
X6R8884	AmiCORE Apheresis Kit - Single Needle with Two Platelet Containers; PAS Connector	47572	1

1) Physical manufacturer name and address:

Fenwal International, Inc.
 Carretera Sanchez Km 18.5
 Parque Industrial Itabo, Zona Franca Ind. de S.C., Haina
 DOMINICAN REPUBLIC