FRESENIUS KABI

EC DECLARATION OF CONFORMITY

Annex II of Directive 93/42/EEC
according to EC-certificate No. G1 047402 0077 Rev. 00
and EC-certificate No. G7 047402 0050 Rev. 01
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, CE0123

Blood Processing Devices

Refer to attachment
(Product name)

Refer to attachment
(Article number)

G7 047402 0050 Rev. 01
(No. of Design Examination Certificate)

Class III

We

Fresenius Kabi AG
61346 Bad Homburg, Germany

manufacturer of the above products, hereby declare under our sole responsibility 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	19 December 2019	Yvonne DeBartolo, Senior Director Global Strategies and Compliance
Place of Issue	Date of Issue	Name (printed letters), Position and Signature of Authorized Person

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

FRESENIUS KABI

Attachment to EC Declaration of Conformity regarding

Blood Processing Devices

Article number	Product name	GMDN	Physical manufacturer name and address
RGB8110B	InterSol solution with male luer lock connector 500 ML	47125	1
DGB8110B	InterSol solution with female luer lock connector 500 ML	47125	1
RGR8109B	InterSol solution 280 ML	47125	1
RGR8114B	InterSol solution 200 ML	47125	1

1) Physical manufacturer name and address:
Fenwal France SAS
Etaille, 36-400 La Chatre
FRANCE