



## 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)

### **Disposables for Apheresis and Cell Separation**

Refer to attachment  
(Product Name)

Refer to attachment  
(Article Code)

Class  IIa -  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.

Emmer-Compascuum, 8 Mar. 2018  
Place and date of issue

Wilma Hilhorst, Manager Regulatory Affairs, BU TCT  
Name (printed letters), position and signature of authorized person

Valid starting with the original date of the document until product change  
Expiry date of Certificate: 07 Jun. 2022



**Attachment to EC Declaration of Conformity**  
**Disposables for Apheresis and Cell Separation**

Article Code	Product Name	GMDN
9007231	P1Y White Blood Cell Set - JAPAN	47572
9007251	C4Y White Blood Cell Set - JAPAN	47572
9007291	RVY-White Blood Cell Set - JAPAN	47572
9007301	Transfer bag 500 ml	47572
9007321	Spike port with LL female	47572
9007341	Bone Marrow - (BMSC) - Bag Set	47572
9008271	C4L Platelet Set (5-day storage) - JAPAN	47572
9400201	C5L Platelet Set (5-day storage)	47572
9400207	C5L Platelet Set	47572
9400208	C5L Platelet Set (5-day storage) for CN	47572
9400211	S5L Platelet Set (5-day storage) SN	47572
9400212	S5L Platelet Set	47572
9400213	S5L Platelet Set	47572
9400217	S5L Platelet Set	47572
9400218	S5L Platelet Set (5-day storage) SN for CN	47572
9400221	C5LT (C5L Triple PLT bag)	47572
9400227	C5LT (C5L Triple PLT bag)	47572
9400301	C4Y White Blood Cell Set	47572
9400321	C4L Platelet Set (5-day storage)	47572
9400361	RVY White Blood Cell Set	47572
9400371	C4L Platelet Set - 5 day storage	47572
9400401	PL1 Plasma Exchange Set	47572
9400407	PL1 Plasma Exchange Set	47572
9400408	PL1 Plasma Exchange Set for CN	47572
9400411	P1R Plasma Treatment Set	47572
9400417	P1R Plasma Treatment Set	47572
9400418	P1R Plasma Treatment Set for CN	47572
9400421	P1Y White Blood Cell Set	47572
9400427	P1Y White Blood Cell Set	47572
9400431	P1YA White Blood Cell Set	47572
9400437	P1YA White Blood Cell Set	47572
9400438	P1YA White Blood Cell Set for CN	47572
9400451	TPE Plasma Exchange Set USA	47572