



## **EC DECLARATION OF CONFORMITY**

Annex II excluding (4) of Directive 93/42/EEC  
according to EC-certificate No. G1 047402 0082 Rev. 00, Expiration Date 26 May 2024  
issued by Notified Body (TÜV Süd Product Service GmbH,  
Ridlerstrasse 65, 80339 Munich, Germany, Identification Number 0123)

### **Transfer Sets incl. Accessories**

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.

Friedberg, 15 June 2020  
Place and date of issue/

  
Susanne Lang, Manager Regulatory Affairs, TCT Division  
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**

### **Transfer Sets incl. Accessories**

Article Code	Product Name	GMDN
C5000	CompoStop® FlowFlex 3F T&B - 100/600/1300 - PLT Pooling - processing and leuko reduction system	44037
CT52600	CompoStop® Flow-Flex 3F T&B - 100/600/1300 - 6-PLT Pooling system	44037
ED01CAA	Compoflex® 2F PLT pooling system - LuerF	44034
EQ02ZAA	Compoflex® 4F - Empty - 60 - IP	46347
EQ06A0E	Compoflex® 4F - RCC storage system for pediatric RCC DINCH	46347
EQ06A0H	Compoflex® 4F - PLT storage system for pediatric RCC/PLT DINCH	46347
ET011AA	Compoflex® 3F - Empty - PDS-V	44037
FD51600	CompoStop™ Flex 2F - PLT processing and leuko reduction system	44034
FT52600	CompoStop™ Flex 3F T&B - PLT Pooling system	44037
GT52600	CompoStop™ FlowFlex 3F T&B - PLT Pooling system	44037
P4158	Compoflex® 1F - Empty - 150	44033
P4159	Compoflex® 4F - Empty - 150	46347
P4164	Compoflex® 1F - Empty - 400	44033
P4165	Compoflex® 3F - Empty - 400	44037
P4170	Compoflex® 1F - Empty - 500 - Luer	44033
P4201	Compoflex® 2F - Empty - 600	44034
P4206	Compoflex® 1F - Empty - 100 - Sampling system	44033
P4207	Compoflex® 1F - Empty - 20 - Sampling system	44033
P4208	Compoflex® 3F T&B Stemcare processing set	44037
P4213	Compoflex® 1F Poolbag - 600 ml	44033
P4220	Compoflex® 1F Empty 600	44033
P4224	Compoflex® 4F - Platelet storage system for pediatric platelets	46347
P4226	Compoflex® 4F Transfer system	46347
P4232	Compoflex® 6F Transfer set	47885
P4235	Compoflex® 4F PLT storage system	46347
P4236	Compoflex® 1F Empty 600	44033
PD51600	CompoStop® Flex 2F - PLT processing and leuko reduction system 100/1300	44034
PD516AA	CompoStop® CI 2F - PLT pooling/processing set	44034
PD516AB	CompoStop® Flex 2F - PLT processing - leuko reduction system	44034
PT52600	CompoStop® Flex 3F T&B - 100/600/1300 - 7-PLT Pooling system	44037
PT526AA	CompoStop® CI 3F T&B - PLT pooling/processing set	44037
PT526AB	CompoStop® Flex 3F T&B - PLT Pooling - processing - leuko reduction system	44037
T2110	Compoflex® 1F PLT storage - 1300	44033
T2131	Compoflex® Transferbag - 600 - PD-V	44033

Article Code	Product Name	GMDN
T2222	Compoflex® 2F - empty - PDS-V	44034
T2226	Compoflex® 2F empty 600 - PDS-V	44034
T2378	Compoflex® 3F - Empty 600 ml - PDS-V + Luer	44037
T3901	Composelect® 2F - dockable PLASMA system	44034
T4049	Composelect® 1F - dockable PLASMA system	44033
T5003	CompoStop® Flex 3F - 100/600/1300 - PLT processing and leuko reduction system	44037
8001229	1-BB-300-E	44033
8001230	1-BB-300-E	44033