



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