



## EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II  
(Implantable Class IIb Devices and Class III Devices)

**No. G70 037258 0060 Rev. 00**

### Manufacturer:

**Fresenius Kabi AG**

Else-Kröner-Str. 1  
61352 Bad Homburg  
GERMANY

SRN Manufacturer - DE-MF-000009273

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.

The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.

Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.

In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapter I is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G70 037258 0060 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G70_037258_0060_Rev.00)

**Report No.:** 713258444

**Valid from:** 2026-03-26

**Valid until:** 2031-03-25

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2026-03-26



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**Classification:** Class III  
**Basic UDI-DI:** 081002044BloodDonationND  
**Intended Purpose:** Blood Donation Systems are intended for the collection, processing, and/or filtration and storage of whole blood and/or blood components.  
**Device(s):**

- CompoFlex
- CompoFlow
- Composelect

Number	Device Name	Article number
1	CompoFlow 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	D3321AA
2	CompoFlow 4F 63 ml CPD/100 ml SAGM - PDS-V	DQ31150
3	CompoFlow 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	DQ31250
4	CompoFlow 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	DQ312CC
5	CompoFlow 4F 63 ml CPD/100 ml SAG-M – WBf - PDS-V	DQ31555
6	CompoFlow 4F 63 ml CPD/100 ml SAG-M - WBf - PDS-V	DQ315CC
7	CompoFlow 4F 63 ml CPD/100 ml SAG-M – WBf - PDS-V	DQ315IL
8	CompoFlow 4F 63 ml CPD/100 ml SAG-M – RCC/PLT - PDS-V	DQ31850
9	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M – PDS-V	DQ32150
10	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	DQ32155
11	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M – RCC – PDS- V	DQ32250
12	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M – RCC – PDS- V	DQ32255
13	CompoFlow 4F T&B 66.5 ml CPD/105 ml SAG-M – RCC – PDS- V	DQ32260
14	CompoFlow 4F T&B 66.5 ml CPD/105 ml SAG-M – RCC – PDS- V	DQ32265
15	CompoFlow 4F T&B 70 ml CPD/110 ml SAG-M – RCC – PDS- M	DQ322AG



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16	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M – RCC – PDS-V	DQ322AI
17	CompoFlow 4F T&B 66.5 ml CPD/105 ml SAG-M – RCC – PDS-V	DQ322AP
18	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	DQ322CC
19	CompoFlow 4F T&B 70 ml CPD/110 ml SAG-M - RCC - PDS-V	DQ322DE
20	CompoFlow 4F T&B 70 ml CPD/110 ml SAG-M – RCC – PDS-V	DQ322NL
21	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M – RCC/PLASMA - PDS-V	DQ32350
22	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M - RCC/PLASMA - PDS-V	DQ323CC
23	CompoFlow 4F 63 ml CPD/100 ml SAG-M – RCC - PDS-V (F)	DQ362HF
24	CompoFlow 4F 63 ml CPD/100 ml SAG-M – RCC - PDS-V	DQ362HM
25	CompoFlow 4F T&B 63 ml CPD/100 ml SAG-M + PDS-V	DQ371CL
26	CompoFlow 4F 63 ml CPD/100 ml PAGGS-M – Wbf - PDS-V	DQ41555
27	CompoFlow 4F 70 ml CPD/110 ml PAGGS-M – Wbf - PDS-V	DQ41575
28	CompoFlow 4F 63 ml CPD/100 ml PAGGS-M - Wbf - PDS-V	DQ415CC
29	CompoFlow 4F T&B 63 ml CPD/100 ml PAGGS-M – RCC – PDS-V	DQ42255
30	CompoFlow 4F T&B 70 ml CPD/110 ml PAGGS-M – RCC – PDS-V	DQ42271
31	CompoFlow 4F T&B 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	DQ422CC
32	CompoFlow 3F 63 ml CPD/100ml SAG-M – PDS-V	DT31150
33	CompoFlow 3F 63 ml CPDA-1 - PDS-V	DT311IL
34	CompoFlow 3F T&B 63 ml CPD/100 ml SAG-M – PDS-V	DT32150
35	CompoFlow 3F T&B 63 ml CPD/100ml SAG-M - PDS-V	DT32155
36	CompoFlow 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	DV322IN



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37	CompoFlow 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	DV322IT
38	CompoFlow 5F T&B 63 ml CPD/100 ml SAG-M RCC/PL - PDS-V	DV323AA
39	CompoFlow 4F 63 ml CPD/100 ml PAGGS-M – Wbf - PDS-V	HQ41555
40	CompoFlow 4F 70 ml CPD/110 ml PAGGS-M – Wbf - PDS-V	HQ41575
41	CompoFlow 4F 63 ml CPD/100 ml PAGGS-M – Wbf - PDS-V	HQ415AI
42	CompoFlow 4F T&B 63 ml CPD/100 ml PAGGS-M – RCC – PDS-V	HQ42250
43	CompoFlow 4F T&B 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	HQ42255
44	CompoFlow 4F T&B 70 ml CPD/110 ml PAGGS-M - RCC - PDS-V	HQ42271
45	CompoFlow 4F T&B 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	HQ422AI
46	Composelect 4F T&B 70 ml CPD/110 ml PAGGS-M - RCCf - PDS-V	HQ422CD
47	CompoFlow 4F T&B 70 ml CPD/110 ml PAGGS-M - RCC - PDS-V	HQ422NL
48	Composelect 4F 63 ml CPD/100 ml PAGGS-M - Wbf - PDS-V	NQ41555
49	Composelect 4F 70 ml CPD/110 ml PAGGS-M - Wbf - PDS-V	NQ41575
50	Composelect 4F T&B 63 ml CPD/100 ml PAGGS-M – RCC – PDS-V	NQ42250
51	Composelect 4F T&B 70 ml CPD/110 ml PAGGS-M - RCC - PDS-V	NQ42271
52	Composelect 4F T&B 66.5 ml CPD/105 ml PAGGS-M RCC - PDS-V	NQ422FR
53	Composelect 5F T&B 66.5 ml CPD/105 ml PAGGS-M - RCC/PLASMA - PDS-V	NV423FR
54	Compoflex 1F 35 ml CPDA-1 – PDS-V	R111130
55	Compoflex 1F 49 ml CPDA-1 – PDS-V	R111140
56	Compoflex 1F 63 ml CPDA-1 – PDS-V	R111150
57	Compoflex 1F 63 ml CPDA-1	R111151



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58	Compoflex 1F 63 ml CPDA-1 – PDS-V	R111159
59	Compoflex 2F 49 ml CPDA-1 – PDS-V	R211140
60	Compoflex 2F 49 ml CPDA-1 – PDS-V	R211144
61	Compoflex 2F 63 ml CPDA-1 – PDS-V	R211150
62	Compoflex 2F 63 ml CPDA-1 – PDS-V	R211156
63	Compoflex 2F 63 ml CPDA-1	R211159
64	Compoflex 2F 63 ml CPDA-1 – PDS-V	R211171
65	Compoflex 2F 63 ml CPDA-1 – PDS-V	R211174
66	Compoflex 3F 49 ml CPDA-1 – PDS-V	R311142
67	Compoflex 3F 63 ml CPDA-1 – PDS-V	R311150
68	Compoflex 3F 63 ml CPDA-1 – PDS-V	R311157
69	Compoflex 3F 63 ml CPDA-1 – PDS-V	R311161
70	Compoflex 3F 63 ml CPDA-1 – PDS-V	R311165
71	Compoflex 3F 35 ml CPD/55 ml SAG-M - PDS-V	R331131
72	Compoflex 3F 49 ml CPD/78 ml SAG-M - PDS-V	R331141
73	Compoflex 3F 63 ml CPD/100 ml SAG-M – PDS-V	R331150
74	Compoflex 3F 63 ml CPD/100 ml SAG-M	R331162
75	Compoflex 3F 63 ml CPD/100 ml SAG-M – PDS-V	R331165
76	Compoflex 3F 63 ml CPD/100 ml SAG-M – PDS-V	R331172
77	Compoflex 3F 63 ml CPD/100 ml SAG-M - PDS-V	R331173
78	Compoflex 3F 63 ml CPD/100 ml SAG-M - PDS-V	R331179
79	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R332150
80	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R332153
81	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R332155



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82	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R332162
83	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R332163
84	Compoflex 3F T&B 49 ml CPD/80 ml SAG-M - PDS-V	R332165
85	Compoflex 4F 63 ml CPDA-1 - PDS-V	R411157
86	Compoflex 4F 63 ml CPD/100 ml SAG-M - PDS-V	R431150
87	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432153
88	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432158
89	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432162
90	Compoflex 4F T&B 49 ml CPD/80 ml SAG-M - PDS-V	R432163
91	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432164
92	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432165
93	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432166
94	Compoflex 2F 63 ml CPDA-1 - PDS-V	RD11150
95	Composelect 2F 70 ml CPDA-1 WBf + PDS-V	RD115DE
96	Compoflex 4F 63 ml CPD/100 ml SAG-M - PDS-V	RQ31150
97	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ31250
98	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ312AA
99	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V (F)	RQ312HF
100	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ312HM
101	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ312IN
102	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ312RO
103	Composelect 4F 63 ml CPD/100 ml SAG-M - WBf - PDS-V	RQ31555



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104	Composelect 4F 66.5 ml CPD/105 ml SAG-M – WBf - PDS-V	RQ31565
105	Composelect 4F 63 ml CPD/100 ml SAG-M - WBf - PDS-V	RQ315AC
106	Composelect 4F 63 ml CPD/100 ml SAG-M - WBf - PDS-V	RQ315CC
107	Composelect 4F 63 ml CPD/100 ml SAG-M - WBf - PDS-V	RQ315IT
108	Composelect 4F 63 ml CPD/100 ml SAG-M – RCC/PLT - PDS-V	RQ31850
109	Composelect 4F T&B 63 ml CPD/100 ml SAG-M – RCC – PDS-V	RQ32250
110	Composelect 4F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ32251
111	Composelect 4F T&B 63 ml CPD/100 ml SAG-M – RCC – PDS-V	RQ322CC
112	Composelect 4F T&B 63 ml CPD/100 ml SAG-M – RCC – PDS-V	RQ322GR
113	Composelect 4F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ322ID
114	Composelect 4F 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RQ322JD
115	Composelect 4F T&B 66.5 ml CPD/105 ml SAG-M – RCC - PDS-V	RQ322UK
116	Composelect 4F T&B 63 ml CPD/100 ml SAG-M – RCC/PLASMA - PDS-V	RQ323CC
117	Composelect 4F T&B 66.5 ml CPD/105 ml SAG-M - RCC/PLASMA - PDS-V	RQ323UK
118	Composelect 4F T&B 63 ml CPD/100 ml SAG-M – WBf - PDS-M	RQ325DE
119	Composelect 4F 49 ml CPD/80 ml SAG-M – RCC - PDS-V	RQ362BM
120	Composelect 4F 63 ml CPD/100 ml PAGGS-M – WBf - PDS-V	RQ41555
121	Composelect 4F 63 ml CPD/100 ml PAGGS-M – WBf - PDS-V	RQ415CC
122	Composelect 4F T&B 70 ml CPD/110 ml PAGGS-M – RCC – PDS-V	RQ42271



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123	Composelect 4F T&B 63 ml CPD/100 ml PAGGS-M – RCC – PDS-V	RQ422CC
124	Composelect 4F T&B 63 ml CPD/100 ml PAGGS-M – RCC – PDS-V	RQ422HN
125	Compoflex 1F 49 ml CPDA-1 – PDS-V	RS11140
126	Compoflex 1F 63 ml CPDA-1 – PDS-V	RS11150
127	Compoflex 1F 70 ml CPDA-1	RS111DE
128	Compoflex 1F 63 ml CPDA-1	RS111GB
129	Compoflex 3F 63 ml CPD/100 ml SAG-M – PDS-V	RT31150
130	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	RT32150
131	Composelect 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RV322AA
132	Composelect 5F T&B 63 ml CPD/100 ml SAG-M – RCC - PDS- V (F)	RV322HF
133	Composelect 5F T&B 63 ml CPD/100 ml SAG-M – RCC - PDS- V	RV322HM
134	Composelect 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RV322IN
135	Composelect 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	RV322PH
136	Composelect 5F T&B 66.5 ml CPD/105 ml SAG-M - RCC/PLASMA - PDS-V	RV323FR
137	Composelect 5F T&B 66.5 ml CPD/105 ml PAGGS-M - RCC/PLASMA - PDS-V	RV423HM
138	CompoFlow 4F 70 ml CPD/110 ml SAG-M – WBf - PDS-V	DQ31575
139	Compoflex 2F 35 ml CPDA-1 - PDS-V	R211132
140	Compoflex 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R332152
141	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	RQ32150
142	Compoflex 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	R432150



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Product Service

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The validity of this certificate ./.  
 depends on conditions and/or  
 is limited to the following:

### Revision History:

Rev.	Dated	Report	Description
00	2026-03-26	713258444	Initial issuance