



EC DECLARATION OF CONFORMITY

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

Transfusion Accessories ACD-A&CPD

Refer to attachment
(Product name)

Refer to attachment
(article number)

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.

Friedberg, 21st October 2020
Place and date of issue

Dieter Fries, Director 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**

Transfusion Accessories

Article Code	Description	GMDN
TS12002	CPD 250 ml	46812
TS14004	ACD-A 700 ml	46812
TS14005	ACD-A 500 ml	46812
TS14006	ACD-A 500 ml	46812
TS14008	ACD-A 1000 ml	46812
TS14009	ACD-A 1000 ml	46812
TS14010	ACD-A 1000 ml	46812
TS14011	ACD-A 1000 ml	46812
TS14012	ACD-A 500 ml	46812
TS14013	ACD-A 500 ml	46812
MD14001	ACD-A 1000 ml – Safe Lock	46812
MD14002	ACD-A 1000 ml – Luer Lock Female	46812
TS14014	ACD-A 700 ml	46812
TS14015	ACD-A 500 ml	46812
TS14016	ACD-A 500 ml	46812
TS14018	ACD-A 1000 ml	46812
TS14019	ACD-A 1000 ml	46812
TS14020	ACD-A 1000 ml	46812
TS14021	ACD-A 1000 ml	46812
TS14022	ACD-A 500 ml	46812
TS14023	ACD-A 500 ml	46812
MD14011	ACD-A 1000 ml – Safe Lock	46812
MD14012	ACD-A 1000 ml – Luer Lock Female	46812

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