



REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

Determina Dirigenziale N. 41 del 22/01/2025

Proponente: Il Direttore UOC PROVVEDITORATO ED ECONOMATO

Oggetto: FORNITURA PLURIENNALE DI SISTEMI E PRODOTTI PER MEDICINA TRASFUSIONALE (ADESIONE AZIENDALE EX DEL DG NN. 566/2024 E 586/2024) –CAMBIO CODICE LOTTO N.9 - DITTA FRESENIUS KABI ITALIA SRL.

PUBBLICAZIONE

In pubblicazione dal 22/01/2025 e per il periodo prescritto dalla vigente normativa in materia (art.8 D.Lgs 14/2013, n.33 e smi)

ESECUTIVITA'

Atto immediatamente esecutivo

TRASMISSIONE

La trasmissione di copia della presente Deliberazione è effettuata al Collegio Sindacale e ai destinatari indicati nell'atto nelle modalità previste dalla normativa vigente. L'inoltro alle UU. OO. aziendali avverrà in forma digitale ai sensi degli artt. 22 e 45 D.gs. n° 82/2005 e s.m.i. e secondo il regolamento aziendale in materia.

UOC AFFARI GENERALI

Direttore Eduardo Chianese

ELENCO FIRMATARI

Teresa Capobianco - UOC PROVVEDITORATO ED ECONOMATO

Per delega del Direttore della UOC AFFARI GENERALI, il funzionario Mauro Ottaiano

Oggetto: FORNITURA PLURIENNALE DI SISTEMI E PRODOTTI PER MEDICINA TRASFUSIONALE (ADESIONE AZIENDALE EX DEL DG NN. 566/2024 E 586/2024) –CAMBIO CODICE LOTTO N.9 - DITTA FRESENIUS KABI ITALIA SRL.

DIRETTORE UOC PROVVEDITORATO ED ECONOMATO

A conclusione di specifica istruttoria, descritta nella narrazione che segue, si rappresenta che ricorrono i presupposti finalizzati all'adozione del presente provvedimento, ai sensi dell'art. 2 della Legge n. 241/1990 e s.m.i. e, in qualità di responsabile del procedimento, dichiara l'insussistenza del conflitto di interessi, ai sensi dell'art. 6bis della legge 241/90 e s.m.i.

PREMESSO CHE

- quest'AORN con Deliberazione del D.G. n.566/2024, qui integralmente trascritta, ha aderito alla Convenzione stipulata dalla So.re.sa. Spa. concernente l'affidamento della fornitura quinquennale di Sistemi e prodotti per medicina trasfusionale destinati ai Servizi Immunotrasfusionali (Det. So.re.sa. Spa. n.256/2023), secondo il dettaglio riportato nel relativo prospetto riepilogativo (già allegato n.5) e per l'importo complessivo di € 2.369.877,15 Iva esclusa;

-la stessa Azienda con successiva deliberazione del DG n.586/2024 ha proceduto - sulla base dei quantitativi rideterminati dalla succitata Società relativamente al lotto n. 9, oggetto di adesione - alla parziale modifica del precedente provvedimento , *"come dettagliato nell'allegato 3, per un importo complessivo di € 1.476.139,15 Iva esclusa"*;

- in esecuzione dei provvedimenti richiamati, il suddetto lotto è in capo alla Ditta FRESENIUS KABI ITALIA SRL e ad oggi è in corso rapporto contrattuale (contratto informatico n. 4600300006 - CIG derivato n. B26F8F82F2) ;

VISTA la nota Prot.n.178/2025, acquisita a mezzo pec (pec dell'08/01/2025 - allegato n.1), con cui la So.re.sa. Spa. - relativamente al medesimo lotto - ha autorizzato il *"cambio codice prodotto da T2241 a prodotto PD11150"*, secondo la documentazione tecnica di pertinenza ed *"alle medesime condizioni economiche contrattuali"*;

ESAMINATA tutta la documentazione innanzi richiamata allegata alla presente ed in atti giacente;
RITENUTO, pertanto, di prendere atto - relativamente al lotto n.9 presente nella summenzionata adesione aziendale - del cambio codice prodotto (*recte*: sacca doppia per auto donazione da 450 ml), proposto dalla Ditta FRESENIUS KABI ITALIA SRL ed autorizzato dalla So.re.sa. Spa., come riportato in premessa e qui espressamente trascritto;

ATTESTATA la legittimità della presente determinazione, che è conforme alla vigente normativa in materia

DETERMINA

per le causali in premessa, che qui si intendono integralmente richiamate e trascritte, di:

I – PRENDERE ATTO - relativamente al lotto n.9 presente nella summenzionata adesione aziendale - del cambio codice prodotto (*recte*: sacca doppia per auto donazione da 450 ml), proposto dalla Ditta FRESENIUS KABI ITALIA SRL ed autorizzato dalla So.re.sa. Spa., come riportato in premessa e qui espressamente trascritto;

II- PRECISARE CHE il presente provvedimento non comporta alcuna spesa aggiuntiva per questo Ente, rimanendo invariate le condizioni economiche contrattuali ;

Determinazione Dirigenziale



REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
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III- NOTIFICARE lo stesso provvedimento alla succitata Ditta;

IV - TRASMETTERE copia del medesimo al Collegio Sindacale, come per legge, ed alle UU.OO.CC. Gestione Risorse Economico - Finanziarie, Immunoematologia e Centro Trasfusionale, Farmacia Ospedaliera, oltreché al Dipartimento Servizi Sanitari per quanto di rispettiva competenza.

IL DIRETTORE
UOC PROVVEDITORATO – ECONOMATO
Dott.ssa Teresa Capobianco

Determinazione Dirigenziale

Il presente atto, in formato digitale e firmato elettronicamente, costituisce informazione primaria ed originale ai sensi dei combinati disposti degli artt. 23-ter, 24 e 40 del D.Lgs. n. 82/2005. Eventuale riproduzione analogica, costituisce valore di copia semplice a scopo illustrativo.



REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

Determinazione Dirigenziale

Il presente atto, in formato digitale e firmato elettronicamente, costituisce informazione primaria ed originale ai sensi dei combinati disposti degli artt. 23-ter, 24 e 40 del D.Lgs. n. 82/2005. Eventuale riproduzione analogica, costituisce valore di copia semplice a scopo illustrativo.

provveditorato@ospedale.caserta.it

Da: Per conto di: a.amendola@soresa.it <posta-certificata@pec.aruba.it>
Inviato: mercoledì 8 gennaio 2025 09:47
A: tender-it@fki-srl.legalmail.it; provveditorato@pec.aslavellino.it;
area.provveditorato@pec.aslbenevento.it; servizio.provveditorato@pec.aslcaserta.it;
acquisizione.beni@pec.aslna1centro.it; provveditorato@pec.aslnapoli2nord.it;
sabs@pec.aslnapoli3sud.it; provveditore@pec.aslsalerno.it;
provveditorato@pec.istitutotumori.na.it; abse.aocardarelli@pec.it;
provveditorato.santobono@pec.it; provveditorato.ospedalideicolli@pec.it;
provveditorato.economato@pec.sangiovannieruggi.it;
ufficio.gare@pec.aornmoscati.it; provveditorato@pec.ao-rummo.it;
provveditorato@ospedalecasertapec.it; protocollo.policliniconapoli.it@pec.it;
respproveconomato.aou@pec.it
Oggetto: ANOMALIA MESSAGGIO: I: Autorizzazione cambio codici- FORNITURA DI SISTEMI E PRODOTTI PER MEDICINA TRASFUSIONALE DESTINATI AI SERVIZI IMMUNOTRASFUSIONALI (SIT) DELLE AA SS DELLA REGIONE CAMPANIA – ID GARA 9119509 - LOTTO 9" - COMUNICAZIONE CAMBIO CODICE DA
Allegati: postacert.eml (9,91 MB)

Anomalia nel messaggio

Il giorno 08/01/2025 alle ore 09:47:08 (+0100) è stato ricevuto il messaggio "I: Autorizzazione cambio codici- FORNITURA DI SISTEMI E PRODOTTI PER MEDICINA TRASFUSIONALE DESTINATI AI SERVIZI IMMUNOTRASFUSIONALI (SIT) DELLE AA SS DELLA REGIONE CAMPANIA ? ID GARA 9119509 - LOTTO 9" - COMUNICAZIONE CAMBIO CODICE DA PRODOTTO T2241 A PR" proveniente da "a.amendola@soresa.it" ed indirizzato a:
provveditorato@ospedalecasertapec.it
Tali dati non sono stati certificati per il seguente errore:
la firma digitale del messaggio non risulta attendibile
Il messaggio originale è incluso in allegato.

Da: Anna Amendola <a.amendola@soresa.it>
Inviato: mercoledì 8 gennaio 2025 09:47
A: tender-it@fki-srl.legalmail.it; provveditorato@pec.aslavellino.it;
area.provveditorato@pec.aslbenevento.it; servizio.provveditorato@pec.aslcaserta.it;
acquisizione.beni@pec.aslna1centro.it; provveditorato@pec.aslnapoli2nord.it;
sabs@pec.aslnapoli3sud.it; provveditore@pec.aslsalerno.it;
provveditorato@pec.istitutotumori.na.it; abse.aocardarelli@pec.it;
provveditorato.santobono@pec.it; provveditorato.ospedalideicolli@pec.it;
provveditorato.economato@pec.sangiovannieruggi.it;
ufficio.gare@pec.aornmoscati.it; provveditorato@pec.ao-rummo.it;
provveditorato@ospedalecasertapec.it; protocollo.policliniconapoli.it@pec.it;
respprovveconomato.aou@pec.it
Oggetto: l: Autorizzazione cambio codici- FORNITURA DI SISTEMI E PRODOTTI PER
MEDICINA TRASFUSIONALE DESTINATI AI SERVIZI IMMUNOTRASFUSIONALI (SIT)
DELLE AA SS DELLA REGIONE CAMPANIA – ID GARA 9119509 - LOTTO 9" -
COMUNICAZIONE CAMBIO CODICE DA PRODOTTO T2241 A PR
Allegati: sra 178-2025 autorizzazione_cambio_codici (5).pdf; SoReSa_2024_19915
_"FORNITURA DI SISTEMI E PRO.pdf; CL_Fresenius Kabi AG_Is_Ila_Ilb_037258
0044 Rev. 00.pdf; comunicazione cambio da T2241 a PD11150.pdf;
Confirmation_Letter_MDR_FK MedTech_V01.pdf; DoC_Blood Donation Systems and
Accessories Class Ilb 25 May 2021.pdf; FreseniusKabiAG_EC Certificate Annex II
excluding (4)_G1 047402 0082 Rev. 00_May2020.pdf

Con la presente si trasmette SoReSa-0000178-2025 08-01-2025 con i relativi allegati.
Distinti saluti.



[Nota di riservatezza: Il presente messaggio, corredato dei relativi allegati, contiene informazioni da considerarsi strettamente riservate ed è destinato esclusivamente al destinatario sopra indicato, il quale è l'unico autorizzato ad usarlo, copiarlo e, sotto la propria responsabilità, a diffonderlo. Chiunque ricevesse questo messaggio per errore o comunque lo leggesse senza esserne legittimato è avvertito che trattenerlo, copiarlo, divulgarlo, distribuirlo a persone diverse dal destinatario è severamente proibito. Egli è pertanto pregato di rinviarlo immediatamente al mittente, distruggendone l'originale. Grazie.]

[Confidentiality Notice: This message, together with its annexes, contains information to be deemed strictly confidential and is destined only to the addressee(s) identified above, who only may use, copy and, under his/their responsibility, further disseminate it. If anyone received this message by mistake or reads it without entitlement is forewarned that keeping, copying, disseminating or distributing this message to persons other than the addressee(s) is strictly forbidden and is asked to transmit it immediately to the sender and to erase the original message received. Thank you.]

Ai Sig.ri Direttori Generali

Ai Sig.ri Provveditori

AA.SS.LL., AA.OO., AA.OO.UU., IRCSS

a mezzo pec

e p.c.

Fresenius Kabi Italia S.r.l.

A mezzo pec: tender-it@fki-srl.legalmail.it

Oggetto: Autorizzazione cambio codici- FORNITURA DI SISTEMI E PRODOTTI PER MEDICINA TRASFUSIONALE DESTINATI AI SERVIZI IMMUNOTRASFUSIONALI (SIT) DELLE AA SS DELLA REGIONE CAMPANIA – ID GARA 9119509 - LOTTO 9" - COMUNICAZIONE CAMBIO CODICE DA PRODOTTO T2241 A PRODOTTO PD11150

Con riferimento all' Accordo Quadro in oggetto

vista la richiesta di autorizzazione cambio codici presentata dalla società Fresenius Kabi Italia S.r.l. nell'ambito della suddetta fornitura ed acquisita al protocollo interno con n. SoReSa/0019915/2024

alla luce dell'istruttoria espletata ed acquisito il parere tecnico favorevole circa il cambio codici proposto dalla Ditta

si autorizza, secondo le previsioni del Capitolato Tecnico di gara, alle medesime condizioni economiche contrattuali, il cambio codici come da comunicazione che costituisce parte integrante e sostanziale della presente.

In allegato:

- Comunicazione cambio codice
- Schede tecniche

Distinti saluti.

So.Re.Sa. S.p.A.
Il Responsabile per l'esecuzione dei contratti
Avv. *Giannmarco Massa*

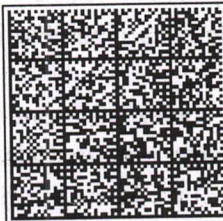
Avv. Fabio Aprea
Direttore Affari Legali

Fabio Aprea

L' art. 23 del Codice dell'Amministrazione Digitale (Decreto Legislativo 7 marzo 2005, n. 82 e s.m.i.), riconosce alle copie analogiche di documenti informatici (es. la stampa di un certificato, un contratto, ecc.) la stessa efficacia probatoria dell'originale informatico da cui sono tratti se la loro conformità non viene espressamente disconosciuta (in giudizio). Diverso il caso in cui la conformità all'originale informatico, in tutte le sue componenti, sia attestata da un pubblico ufficiale autorizzato. In questo caso, infatti, per negare alla copia analogica di documento informatico la stessa efficacia probatoria del documento sorgente si rende necessaria la querela di falso.

Questo regime, di carattere generale, incontra alcune deroghe rispetto alle copie analogiche di documenti amministrativi informatici.

L'art. 23-ter del CAD prevede che sulle copie analogiche di documenti amministrativi informatici possa essere apposto un contrassegno a stampa (detto anche timbro digitale o glifo) che consente di accertare la corrispondenza tra le copie analogiche stesse e l'originale informatico (in esso deve essere codificato, infatti, il documento informatico o le informazioni necessarie a verificarne la corrispondenza all'originale in formato digitale). La verifica avviene grazie ad appositi software che leggono le informazioni contenute nel timbro digitale. I software necessari per l'attività di verifica devono essere gratuiti e messi liberamente a disposizione da parte delle amministrazioni.



Copia conforme di un documento amministrativo informatico formata ai sensi dell'articolo 23-ter, comma 5 del CAD.
Il presente contrassegno digitale Datamatrix contiene informazioni utili alla verifica della corrispondenza del documento all'originale digitale conservato dall'amministrazione proprietaria dello stesso.
Il contrassegno può essere letto con qualsiasi applicazione in grado di decodificare il formato Datamatrix e con gli smartphone dei principali costruttori.
In alternativa, possibile collegarsi al sistema DgsWebOS dell'amministrazione e ricercare dopo l'autenticazione il documento

Impronta del documento digitale originale: 72809c12e9d4db74ab69307f792e7a35

Identificativo del documento digitale originale: 615951

Protocollo: SoReSa-0000178-2025 08-01-2025 09:36:12

Fresenius Kabi AG, 61346 Bad Homburg, Germany

Fresenius Kabi AG

Else-Kröner-Straße 1
61352 Bad Homburg
Deutschland
T +49 6172 686-0
www.fresenius-kabi.com

To whom it may concern

Declaration on the application of Regulation (EU) 2023/607 of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Published in the Official Journal of the European Union on 20 March 2023

We,

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
Germany

as the holder of Certificates listed below and represented by Heinrich Martens, Vice President Regulatory Affairs and nominated Person Responsible for Regulatory Compliance, herewith confirm:

The products falling within the scope of the below listed certificates issued according to the Directive 93/42/EEC are subject to the scope of the Regulation (EU) 2023/607 amending (EU) 2017/745, in particular the amendment of Article 120:

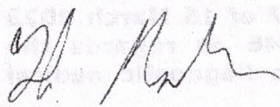
EC Certificate No.	Directive 93/42/EEC	Product Classification
G1 047402 0083 Rev. 00	Annex II excluding (4)	IIa, IIb or III
G2S 047402 0084 Rev. 00	Annex V	Is
G7 047402 0046 Rev. 01	Annex II (4)	III
G7 047402 0087 Rev. 00	Annex II (4)	III
G1 047402 0077 Rev. 00	Annex II excluding (4)	IIa, IIb or III
G7 047402 0050 Rev. 01	Annex II (4)	III
G1 047402 0082 Rev. 00	Annex II excluding (4)	IIa, IIb or III
G2S 047402 0085 Rev. 00	Annex V	Is

The Regulation (EU) 2023/607 is fully applicable for the products covered by the certificates listed above.

The extended period of validity by virtue of paragraph 2 of the Regulation (EU) 2023/607 of these certificates and the respective Declaration of Conformities until the given dates below is hereby confirmed by Fresenius Kabi AG:

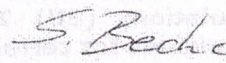
- **31 December 2027** for all class III devices, and for class IIb implantable
- **31 December 2028** for class IIb non-implantable, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

For and on behalf of Fresenius Kabi AG,



i.V.
Heinrich Martens
Vice President Regulatory Affairs
Fresenius Kabi MedTech

DocuSigned by:



i.V.
Dr. Sabine Becke
Director Regulatory Affairs
Fresenius Kabi MedTech

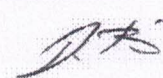
Bad Hersfeld, 21 November 2023

01-047402-0002 Rev. 00	Annex V	is fully or II
02-047403-0004 Rev. 00	Annex V	is fully or II
03-047401-0005 Rev. 01	Annex II (a)	is fully or II
04-047402-0007 Rev. 00	Annex II (a)	is fully or II
05-047403-0007 Rev. 00	Annex II (a)	is fully or II
06-047402-0008 Rev. 01	Annex II (a)	is fully or II
07-047403-0009 Rev. 00	Annex II (a)	is fully or II
08-047402-0010 Rev. 00	Annex V	is fully or II

Attachment to EC Declaration of Conformity

Blood Donation Systems and Accessories

Article Code	Description	GMDN
C2980	CompoFlow® 4F 70 ml CPD/110 ml SAGM - WB + PDS-V	46347
C311153	CompoFlow® 3F 63 ml CPDA-1 - PDS-V	44037
C3321AA	CompoFlow® 3 F T&B 63 ml CPD/100 ml SAGM - PDS-V	44037
C3947	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-V + LM	46347
C3974	CompoFlow® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	47747
C3975	CompoFlow® 5F 63 ml CPD/100ml SAG-M - RCC + PDS-V + LM	47747
C4008	CompoFlow® 4F T&B 70ml CPD/110ml SAG-M - RCC + PDS-V	46347
C4010	CompoFlow® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC + PDS-M	46347
C4015	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-M+L	46347
C4922	CompoFlow® 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	47747
CQ31150	CompoFlow® 4F 63 ml CPD/100 ml SAGM - PDS-V	46347
CQ31250	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
CQ312AA	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
CQ31450	CompoFlow® 4F 63 ml CPD/100 ml SAGM - WB + PDS-V	46347
CQ31555	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - WBf + PDS-V	46347
CQ31575	CompoFlow® 4F 70 ml CPD/110 ml SAG-M - WBf + PDS-V	46347
CQ315AD	CompoFlow® 4F 63 ml CPD/100 ml SAG-M WBf + PDS-V	46347
CQ315AI	CompoFlow® 4F 63 ml CPD/100 ml SAGM - WBf + PDS-V	46347
CQ315AK	CompoFlow® 4F 70 ml CPD/110 ml SAG-M - WBf2 + PDS-V	46347
CQ315IL	CompoFlow® 4F 63 ml CPD/100 ml SAGM - WBf + PDS-V	46347
CQ31850	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - RCC/PLT + PDS-V	46347
CQ32150	CompoFlow® 4F T&B - 63ml CPD/100ml SAGM - PDS-V	46347
CQ321AA	CompoFlow® 4F T&B 63 ml CPD/100 ml SAG-M + PDS-V	46347
CQ321AB	CompoFlow® 4F T&B - 63 ml CPD/100 ml SAG-M - PDS-V	46347
CQ32250	CompoFlow® 4F T&B 63 ml CPD/100 ml SAGM - RCC - PDS-V	46347
CQ32255	CompoFlow® 4F T&B 63 ml CPD/100 ml SAGM - RCC - PDS-V	46347
CQ32260	CompoFlow® 4F T&B - 66.5 ml CPD/105 ml SAG-M - RCC - PDS-V	46347
CQ32265	CompoFlow® 4F T&B - 66.5 ml CPD/105 ml SAG-M - RCC - PDS-V	46347
CQ32271	CompoFlow® 4F T&B 70 ml CPD/110ml SAG-M - RCC - PDS-V	46347
CQ322AG	CompoFlow® 4F T&B 70 ml CPD/110 ml SAG-M - RCC - PDS-M	46347
CQ322AH	CompoFlow® 4F T&B 70 ml CPD/110 ml SAG-M - RCC - PDS-M	46347
CQ322AI	CompoFlow® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
CQ322AM	CompoFlow® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-M+LF	46347
CQ322AN	CompoFlow® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V+LF	46347





**FRESENIUS
KABI**

EC DECLARATION OF CONFORMITY

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

Blood Donation Systems and Accessories

Refer to attachment
(Product name)

Refer to attachment
(article number)

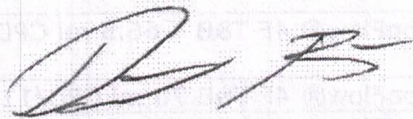
Class ☐ IIa - ☒ IIb

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, 25 May 2021
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.

Changes in this EC Declaration of Conformity are to be implemented based on Article 120 of the MDR (2017/745/EC) and the corresponding guidance documents.

PQ315GR	Composelect® 4F 63 ml CPD/100 ml SAG-M - WBf + PDS-V	46347
PQ31850	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC/PLT + PDS-V	46347
PQ318AD	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC/PLT + PDS-V	46347
PQ32150	Compoflex® 4F T&B - 63ml CPD/100ml SAGM - PDS-V	46347
PQ32250	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
PQ32271	Composelect® 4F T&B 70 ml CPD/110ml SAG-M - RCC - PDS-V	46347
PQ322AB	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
PQ322AD	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
PQ322CC	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
PQ32350	Composelect® 4F T&B 63 ml CPD/100 ml SAG-M - RCC/PLASMA + PDS-V	46347
PQ323CC	Composelect® 4F T&B 63 ml CPD/100 ml SAG-M - RCC/PLASMA + PDS-V	46347
PQ325AA	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - WBf + PDS-M	46347
PQ32RAA	Composelect® 4F T&B - 70 ml CPD/110 ml SAG-M - RCCf + PDS-M	46347
PQ362BM	Composelect® 4F 49 ml CPD/80 ml SAG-M - RCC + PDS-V	46347
PQ41555	Composelect® 4F 63 ml CPD/100 ml PAGGS-M - WBf + PDS-V	46347
PQ41575	Composelect® 4F 70 ml CPD/110 ml PAGGS-M - WBf + PDS-V	46347
PQ415CC	Composelect® 4F 63 ml CPD/100 ml PAGGS-M - WBf + PDS-V	46347
PQ42271	Composelect® 4F T&B 70 ml CPD/110 ml PAGGS-M - RCC - PDS-V	46347
PQ422CC	Composelect® 4F T&B 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	46347
PQ422HN	Composelect® 4F T&B 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	46347
PQT2957	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
PQT3916	Composelect® 4F 63 ml CPD/100 ml SAG-M WB + PDS-V	46347
PQT3922	Composelect® 4F T&B - 66.5 ml CPD/105 ml SAG-M - RCC + PDS-V	46347
PQT3949	Composelect® 4F 66.5 ml CPD/105 ml SAGM - WB + PDS-V	46347
PQT4030	Composelect® 5F T&B 66.5 ml CPD/105 ml SAG-M RCC/PLASMA + PDS-V	47747
PQT4077	Composelect® 4F 66.5 ml CPD/105 ml SAG-M WB+PDS-V	46347
PQT4916	Composelect® 4F 63 ml CPD/100 ml SAG-M WB + PDS-V	46347
PQT4920	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
PS11140	Compoflex® 1F 49 ml CPDA1 - PDS-V	44033
PS11150	Compoflex® 1F 63 ml CPDA1 - PDS-V	44033
PS111AH	Compoflex® 1F - 49 ml CPDA-1 - PDS-V+L	44033
PS111AI	Compoflex® 1F - 63 ml CPDA-1 - PDS-V+L	44033
PS111EA	Compoflex® 1F 63 ml CPDA-1 - Luer M	44033
PS111LA	Compoflex® 1F 63 ml CPDA-1 PDS-V	44033
PS58ZAA	Compoflex® 1F 200 ml SAG-M - LLM + LLF	44033
PT111LA	Compoflex® 3F 63 ml CPDA-1 PDS-V	44037
PT115TW	Composelect® 3F 63 ml CPDA-1 WBf + PDS-V	44037
PT31150	Compoflex® 3F 63 ml CPD/100ml SAGM - PDS-V	44037
PT32150	Compoflex® 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	44037
PV322AD	Composelect® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	47747
PV322AF	Composelect® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	47747

PR

CQ322AP	CompoFlow® 4F T&B - 66.5 ml CPD/105 ml SAG-M - RCC - PDS-V	46347
CQ322CC	CompoFlow® 4F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	46347
CQ322LA	CompoFlow® 4F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
CQ32350	CompoFlow® 4F T&B 63 ml CPD/100 ml SAG-M - RCC/PLASMA + PDS-V	46347
CQ323CC	CompoFlow® 4F T&B 63 ml CPD/100 ml SAG-M - RCC/PLASMA + PDS-V	46347
CQ32R60	CompoFlow® 4F T&B - 66.5 ml CPD/105 ml SAG-M - RCC - PDS-V	46347
CQ341LA	CompoFlow® 4F T&B CPD SAG-M TOTM PDS-V ESP	46347
CQ362AF	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V (F)	46347
CQ362AM	CompoFlow® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
CQ371AA	CompoFlow® 4F T&B - 63ml CPD/100ml SAG-M - PDS-V	46347
CQ41450	CompoFlow® 4F 63 ml CPD/100 ml PAGGS-M - WB + PDS-V	46347
CQ41470	CompoFlow® 4F 70 ml CPD/110 ml PAGGS-M - WB + PDS-V	46347
CQ41555	CompoFlow® 4F 63 ml CPD/100 ml PAGGS-M - WBf + PDS-V	46347
CQ41575	CompoFlow® 4F 70 ml CPD/110 ml PAGGS-M - WBf + PDS-V	46347
CQ415CC	CompoFlow® 4F 63 ml CPD/100 ml PAGGS-M - WBf + PDS-V	46347
CQ42255	CompoFlow® 4F T&B - 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	46347
CQ42271	CompoFlow® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC - PDS-V	46347
CQ422CC	CompoFlow® 4F T&B - 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	46347
CQ422HN	CompoFlow® 4F T&B - 63 ml CPD/100 ml PAGGS-M - RCC - PDS-V	46347
CQC2820	CompoFlow® 4F T&B - 63ml CPD/100ml SAG-M - PDS-V	46347
CQC2988	CompoFlow® 4F T&B - 70 ml CPD/110 ml SAG-M - RCC - PDS-V	46347
CT31150	CompoFlow® 3F 63 ml CPD/100ml SAG-M - PDS-V	44037
CT32150	CompoFlow® 3F T&B 63 ml CPD/100ml SAG-M - PDS-V	44037
CT32155	CompoFlow® 3F T&B 63 ml CPD/100ml SAG-M - PDS-V	44037
CT321AA	CompoFlow® 3F TAB CPD SAG-M PDS-V ESP	44037
CV322AI	CompoFlow® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	44037
CV322LA	CompoFlow® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	44037
CV323AA	CompoFlow® 5F T&B 63 ml CPD/100 ml SAG-M RCC/PL + PDS-V	47747
ET011AA	Compoflex® 3F - Empty - PDS-V	44037
GQ42271	CompoFlow® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC - PDS-V	46347
GQ422NL	CompoFlow® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC - PDS-V	46347
PD11140	Compoflex® 2F 49 ml CPDA1 - PDS-V	47747
PD11150	Compoflex® 2F 63 ml CPDA1 - PDS-V	44034
PD111LA	Compoflex® 2F 63 ml CPDA-1 PDS-V	44034
PQ111LA	Compoflex® 4F 63 ml CPDA-1 PDS-V	44034
PQ31150	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
PQ311LA	Compoflex® 4F 63 ml CPD/100 ml SAG-M PDS-V	46347
PQ31250	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
PQ312AA	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
PQ31450	Composelect® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-V	46347
PQ31451	Composelect® 4F 63 ml CPD/100 ml SAG-M WB + PDS-V	46347
PQ314AA	Composelect® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-V	46347
PQ31555	Composelect® 4F 63 ml CPD/100 ml SAG-M - WBf + PDS-V	46347
PQ31565	Composelect® 4F 66.5 ml CPD/105 ml SAG-M - WBf + PDS-V	46347
PQ31575	Composelect® 4F 70 ml CPD/110 ml SAG-M - WBf + PDS-V	46347
PQ315AC	Composelect® 4F 63 ml CPD/100 ml SAG-M - WBf + PDS-V	46347
PQ315AD	Composelect® 4F 63 ml CPD/100 ml SAG-M WBf + PDS-V	46347
PQ315AE	Composelect® 4F 70 ml CPD/110 ml SAG-M - WBf2 + PDS-V	46347

J.R.

T331159	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331161	Compoflex® 3F - 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331162	Compoflex® 3F 63 ml CPD/100 ml SAG-M	44037
T331164	Compoflex® 3F- 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331165	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331168	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331169	Compoflex® 3F 63CPD/100SAG-M	44037
T331172	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331173	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331178	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331179	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T332150	Compoflex® 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	44037
T332152	Compoflex® 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	44037
T332153	Compoflex® 3F T&B 63 ml CPD/100 ml SAGM - PDSV	44037
T332154	Compoflex® 3F T&B - 63 ml CPD/100 ml SAG-M - PDS-V	44037
T332155	Compoflex® 3F T&B 63 ml CPD/100 ml SAG-M - PDS-V	44037
T332162	Compoflex® 3 F T&B 63 ml CPD/100 ml SAG-M - PDS-V	44037
T332163	Compoflex® 3 F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T3902	Composelect® 4F T&B 70 ml CPD/110 ml PAGGS-M - WB + PDS-M	46347
T3947	Composelect® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-V + LuerM	46347
T3956	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M WB + PDS-V	46347
T3963	Composelect® 5F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-V	47747
T3965	Composelect® 4F 63CPD/100 ml SAG-M - RCC + PDS-V	46347
T3985	Composelect® 4F T&B - 70 ml CPD/110 ml SAG-M - WB + PDS-M	46347
T3986	Composelect® 4F T&B - 63ml CPD/100 ml SAG-M - WB + PDS-M	46347
T3990	Composelect® 4F T&B - 70 ml CPD/110 ml SAG-M - RCC + PDS-M	46347
T3991	Composelect® 4F T&B - 63 ml CPD/100 ml PAGGS-M - WB + PDS-M	46347
T3998	Composelect® 4F T&B 63 ml CPD/100 ml SAG-M - RCC + PDS-M	46347
T4010	Composelect® 4F T&B 70 ml CPD/110ml PAGGS-M - RCC + PDS-M	46347
T4021	Composelect® 4F 63 ml CPD/100 ml SAG-M - WB + PDS-V	46347
T4026	Composelect® 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	47747
T4029	Compoflex® CB Collect 2F 20 ml + 10 ml CPD Composampler V	44034
T4097	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
T411150	Compoflex® 4F - 63 ml CPDA-1 - PDS-V	46347
T411157	Compoflex® 4F 63 ml CPDA-1 - PDS-V	46347
T411163	Compoflex® 4F 63 ml CPDA-1 - PDS-V	46347
T431141	Compoflex® 4F 49CPD/80SAGM - PDS-V	46347
T431142	Compoflex® 4F 49CPD/80SAG-M - PDS-V	46347
T431150	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T431151	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T431156	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T431160	Compoflex® 4F 63 ml CPD/100 ml SAG-M	46347
T431163	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T431167	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T431169	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432150	Compoflex® 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432152	Compoflex® 4F T&B - 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432153	Compoflex® 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432154	Compoflex® 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432158	Compoflex® 4F T&B - 63 ml CPD/100 ml SAG-M - PDS-V	46347

J.F.

PV423HM	Composelect® 5F T&B 66.5 ml CPD/105 ml PAGGS-M RCC/PLASMA + PDS-V	47747
T111130	Compoflex® 1F 35 ml CPDA-1 - PDS-V	44033
T111140	Compoflex® 1F 49 ml CPDA-1 - PDS-V	44033
T111141	Compoflex® 1F 44,8 ml CPDA-1	44033
T111144	Compoflex® 1F 49 ml CPDA-1 - PDS-V	44033
T111145	Compoflex® 1F 49 ml CPDA-1 - PDS-V	44033
T111150	Compoflex® 1F 63 ml CPDA-1 - PDS-V	44033
T111151	Compoflex® 1F 63 ml CPDA-1	44033
T111159	Compoflex® 1F 63 ml CPDA-1 - PDS-V	44033
T111161	Compoflex® 1F 63 ml CPDA-1 - PDS-V	44033
T2107	Compoflex® 1F 63 ml CPDA-1 - PD-V + L	44033
T2109	Compoflex® 1F 63ml CPDA-1 - PDS-V + L	44033
T211132	Compoflex® 2F 35 ml CPDA-1	44034
T211140	Compoflex® 2F 49 ml CPDA-1 - PDS-V	44034
T211144	Compoflex® 2F 49 ml CPDA-1 - PDS-V	44034
T211150	Compoflex® 2F 63 ml CPDA-1 - PDS-V	44034
T211151	Compoflex® 2F 63 ml CPDA-1	44034
T211153	Compoflex® 2F 63 ml CPDA-1	44034
T211155	Compoflex® 2F - 63 ml CPDA-1 - PDS-V	44034
T211156	Compoflex® 2F 63 ml CPDA-1 - PDS-V	44034
T211159	Compoflex® 2F 63 ml CPDA-1	44034
T211169	Compoflex® 2F 63 ml CPDA-1	44034
T211171	Compoflex® 2F 63 ml CPDA-1 - PDS-V	44034
T211172	Compoflex® 2F 63 ml CPDA-1 - PDS-V	44034
T211174	Compoflex® 2F 63 ml CPDA-1 - PDS-V	44034
T2115	Compoflex® 1F 70 ml CPDA-1	44033
T2116	Compoflex® 1F 70 ml CPDA-1 - Luer M	44033
T2118	Compoflex® 1F 63 ml CPDA-1 - Luer M	44033
T2125	Compoflex® 1F 49 ml CPDA-1 - PDS-V	44033
T2127	Compoflex® 1F - 49 ml CPDA-1 - PDS-V+L	44033
T2131	Compoflex® 1F empty - PD-V	44033
T2222	Compoflex® 2F empty - PDS-V	44034
T2226	Compoflex® 2F empty - PDS-V	44034
T2241	Compoflex® 2F - 63 ml CPDA-1 - PDS-V + L	44034
T2375	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V + I	44037
T2378	Compoflex® 3F Empty 600 ml - PDS-V + Luer	44037
T2720	Compoflex® 3F T&B - 70ml CPD/110ml PAGGS-M - PDS-V + Luer	44037
T2950	Compoflex® CB-Collect 2F 20 ml + 10 ml CPD	44034
T2993	Compoflex® CB-collect 1F 20 ml CPD	44033
T2997	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
T311142	Compoflex® 3F 49 ml CPDA-1 - PDS-V	44037
T311150	Compoflex® 3F 63 ml CPDA-1 - PDS-V	44037
T311153	Compoflex® 3F - 63 CPDA-1 PDS-V	44037
T311154	Compoflex® 3F - 63 ml CPDA-1 - PDS-V	44037
T311157	Compoflex® 3F 63 ml CPDA-1 - PDS-V	44037
T311159	Compoflex® 3F 63 ml CPDA-1	44037
T311161	Compoflex® 3F 63 ml CPDA-1 - PDS-V	44037
T311165	Compoflex® 3F 63 ml CPDA-1 - PDS-V	44037
T331131	Compoflex® 3F 35 ml CPD/55 ml SAG-M	44037
T331141	Compoflex® 3F 49 ml CPD/78 ml SAG-M	44037
T331142	Compoflex® 3F 49CPD/80SAG-M	44037
T331150	Compoflex® 3F 63 ml CPD/100 ml SAG-M - PDS-V	44037
T331151	Compoflex® 3F 63 mlCPD/100 ml SAG-M - PDS-V	44037
T331154	Compoflex® 3F 63 ml CPD/100 ml SAG-M	44037

DTB

Fresenius Kabi Italia S.r.l.
Società con Unico Socio Fresenius Kabi Deutschland GmbH
Soggetta a direzione e coordinamento di Fresenius Kabi AG

Isola Della Scala (VR), dicembre 2024

Egregio Utilizzatore,

con la presente desideriamo informarLa riguardo del cambio di prodotto dall'attuale codice T2241 con il nuovo codice PD11150.

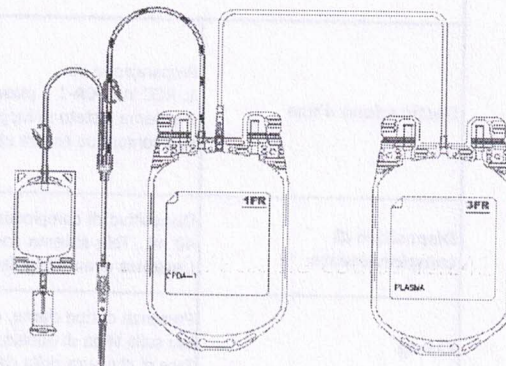
Il codice T2241 è in phase-out dal mercato causa la nuova direttiva MDR inerente i dispositivi medici che vieta l'uso della linea di reinfusione su Sangue Intero.

Il nuovo prodotto ha stessa destinazione d'uso del precedente, ma non contiene la linea di reinfusione collegata alla linea di raccolta del Sangue Intero.

Il nuovo sistema contiene sempre 63 mL di CPDA-1, è realizzato con materiali plastici DEHP e può raccogliere fino a 450 mL di Sangue Intero.

I tubi hanno diametro compatibile con sistemi di connessione sterile SCD.

Etichettatura conforma agli ISBT e con presenza di codici a barre sia del lotto che del REF prodotto.



Ogni confezione è composta da 36 pezzi.

Precisiamo che tale cambio di prodotto non comporterà alcuna variazione del prezzo e delle condizioni di fornitura.

Chiediamo la cortesia di inserire il nuovo codice prodotto nella vostra anagrafica materiale.

Nel rimanere a disposizione per ulteriori chiarimenti cogliamo l'occasione per porgerLe i nostri più distinti saluti.

Fresenius Kabi Italia S.r.l.

Procuratore speciale

Andrea Ferrara



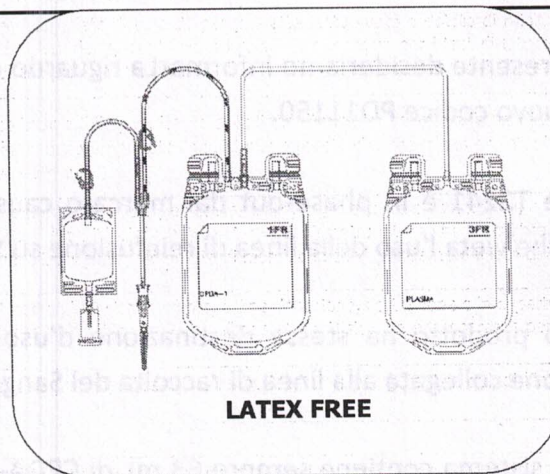
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Capitale Sociale € 7.998.000 int. vers. - Reg. Imprese, Part. IVA e Cod. Fisc. N.: 0352405 023 8 - R.E.A. VR 343254 - R.A.E.E. N.: IT02020000002431

Codice	PD11150
Nome commerciale	Compoflex® 2F 63 ml CPDA1 - PDS-V
Tipologia di prodotto	Sacca doppia T&T CPDA-1 per la raccolta di 450 mL di sangue intero con sistema preassemblato Composampler per raccolta di campioni con sistemi sotto vuoto dotato di minibag da 40 mL.
Prodotto da:	Fresenius Kabi AG D-61346 Bad Homburg
Distribuito da:	Fresenius Kabi Italia S.r.l. Via Camagré, 41 37063 Isola della Scala (VR) T: +39 045 6649311 F: +39 045 6649404 marketing-it@fresenius-kabi.com www.fresenius-kabi.it
Destinazione d'uso	Preparazione di: 1. RCC in CPDA-1 e plasma. Il sistema è stato sviluppato particolarmente per la separazione con apparecchiature automatiche serie Compomat. Può comunque essere utilizzato con qualunque altro dispositivo automatico o manuale.
Dispositivo di campionamento	Dispositivo di campionamento preassemblato completo di camicia per provette sotto vuoto e dotato di minibag da 40 mL. Tale sistema consente, all'inizio della donazione, di utilizzare i primi mL di sangue per i test di laboratorio. L'assenza di anticoagulante lungo la linea di campionamento preserva il test della glicemia da eventuali alterazioni.
Clamp	Presenza di due clamp, una di colore bianco irreversibile posizionata sulla linea di campionamento e l'altra di colore blu sulla linea di donazione. Entrembe le clamp sono progettate con sistema a parete che agevola la perfetta la fase di chiusura della clamp da parte dell'operatore.
Ago	Calibro da 16 Gauge in acciaio conforme alle norme ISO 9626, a parete sottile, taglio a tripla sfaccettatura, ad altissima penetrazione ed a doppia siliconatura. A parità di diametro esterno, il diametro interno ha un calibro maggiorato per un miglior flusso del sangue. L'impugnatura è dotata di marchio in corrispondenza del lato di taglio per un corretto inserimento in vena.
Dispositivo di protezione ago	Il sistema è dotato di "Ago retrattile" (RT Needle Plus) che consente, a fine donazione, l'estrazione e la copertura dell'ago in un'unica operazione, per un elevato grado di protezione dell'operatore. Il sistema è trasparente per una migliore visione del sito di venipuntura.
Copertura dell'ago	Copertura ago termosaldato antimanomissione per impedire aperture accidentali e per garantire quindi l'integrità del prodotto prima dell'utilizzo.
Volume nominale sacche	600/600 mL
Coni frattura (break-off)	Coni frattura a posizionamento forzato predisposti per consentire il flusso degli emocomponenti senza ostruzioni e in modo bidirezionale.
Copertura port	La copertura/protezione dei port è completamente asportabile in fase di apertura per impedire che ritorni in posizione disturbando l'operatore.
Protezione ingresso port	Port perforabili con sezione di ingresso ispessita per garantire una presa migliore durante la fase di inserimento degli spike e quindi aumentare il grado di sicurezza degli operatori.
Film plastico	PVC di grado medicale in Classe VI (plastificato con DEHP) prodotto in conformità alla Farmacopea Europea vigente ed alle ISO 3826. Finitura superficiale studiata per ridurre l'adesività piastrinica e per facilitare la rimozione della sacca dal cestello della centrifuga.
Tubatismi	Tutti i tubatismi sono compatibili con i sistemi di connessione sterile (SCD).
Connessioni a "Y"	Le connessioni a "Y" hanno volume interno ridotto e design tale da minimizzare le turbolenze e quindi l'emolisi ad esse associata.



Codice	PD11150
Nome commerciale	Compoflex® 2F 63 ml CPDA1 - PDS-V
Etichettatura	Conforme alle norme EN 980 Lotto e tipologia del sistema indicati anche con codici a barre in accordo agli standard ISBT, posizionati in modo da rimanere visibili anche dopo etichettatura definitiva da parte della Struttura Trasfusionale.
Soluzione anticoagulante e conservante	CPDA-1: 63 mL Composizione di 1000 mL di CPDA-1: Sodio citrato biidrato 25,3 g; Acido citrico monoidrato 3,277 g; Glucosio Monoidrato 31,9 g; Sodio fosfato acido biidrato 2,51g; Adenina 0,275 g; Acqua per iniezione a 1000 mL.
Conservazione emocomponenti	Sangue intero in CPDA-1: 35 gg a +4°C
Confezionamento	Ogni sistema è confezionato singolarmente con involucro trasparente e provvisto di etichettatura riportante le scadenze. N.Pezzi per cartone: 36
Sterilizzazione	A vapore saturo.
Validità	24 mesi (nel rispetto delle condizioni di stoccaggio).
Condizioni di stoccaggio	Conservare a temperatura tra 0°e 25°C lontano dall'umidità. Proteggere dalla luce diretta. Dopo l'apertura del multipack in PE, utilizzare entro 60 giorni. Una volta aperta la confezione singola, utilizzare entro 10 giorni.
Codice CND e numero repertorio (RDM)	CND: B0101020299 RDM: 2524993
Classificazione	IIb (allegato IX della DDM 93/42/CEE modificata con la Direttiva 2007/47/CE).
Component List	Acciaio, ABS, PC, Polyester, POM

Fresenius Kabi Italia srl DICHIARA

che tutte le informazioni fornite alla Stazione Appaltante nell'ambito ed a motivo della presente offerta, ivi comprese quelle rese a giustificazione della medesima, ai sensi dell'art. 86, comma 5, d.lgs. n.163 del 2006 quali - a titolo esemplificativo e non esaustivo - informazione sui prezzi e sulla qualità dei prodotti offerti, informazioni sugli aspetti tecnici dei prodotti offerti e sul processo produttivo degli stessi, dati economici relativi all'incidenza dei costi di produzione ovvero all'analisi delle componenti dei prodotti offerti, **sono da considerarsi informazioni strettamente riservate e rimangono di proprietà esclusiva di questa società.**

Tali informazioni, di carattere strettamente confidenziale, potranno essere utilizzate esclusivamente dalla Stazione Appaltante e comunque al solo scopo di valutare l'offerta formulata nella presente gara da Fresenius Kabi Italia srl.

Ai sensi dell'art. 13, comma 5, lett. a), d. lgs. n. 163 del 2006, esse non potranno essere rivelate ad altri soggetti e/o diffuse a terzi, fuori dai casi di legittimo esercizio del diritto di accesso agli atti, documenti e provvedimenti della gara da parte degli altri partecipanti alla stessa, comunque nel rispetto del termine previsto dall'art. 13, comma 2, lett. c), d. lgs. n. 163 del 2006 (vale a dire non prima dell'approvazione dell'aggiudicazione della gara) e nei limiti di cui all'art. 13, comma 6, d.lgs.163 del 2006. In ogni caso **Fresenius Kabi Italia srl**, in relazione alle suddette informazioni, dichiara fin da ora di considerarsi controinteressata ad ogni effetto di legge, ed in particolare ai sensi e per gli effetti dell'art. 22, comma 1, lett. c), l. n. 241 del 1990 e degli art. 3 e 6, d.P.R. n. 184 del 2006, richiedendo espressamente che le sia data tempestiva comunicazione, nelle forme di cui all'art. 3 d.P.R. n. 184 del 2006, di ogni eventuale istanza di accesso ai documenti contenenti tali informazioni riservate, formulata ex art. 25, l.n. 241 del 1990, da altri concorrenti alla gara.



Add value.
Inspire trust.

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
CBW 37258	713186567 713198383	- medical_devices@tuvsud.com	-	2024-03-15	1 of 40

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 037258 0044 Rev. 00

Reference: 713186567 | 713198383

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000009273

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification Body for Medical Devices
Ridlerstr. 65
80339 Munich
Germany
tuvsud.com/ps
Hotline: +49 89 50084-747





(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 037258 0044 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-03-15

TÜV SÜD Product Service GmbH
Medical and Health Services

Deepak Kumar

Deepak Kumar
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Franziska Eckert

2024.03.15

18:42:26 +01'00'

Franziska Eckert
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Bags / Freka® Mix Bag and Accessories Basic UDI - 42502737NIV50711s000000C9	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1: CA# Evidence #2: CA#
Enteral Feeding Tubes Transnasal / Freka® Feeding Tubes and Accessories Basic UDI- 42502737NEN60512a000000JW	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00. , NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1: CA# Evidence #2: CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Enteral Feeding Tubes percutaneous / Freka® Intestinal Tubes Basic UDI- 42502737NEN60122b000000GJ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Feeding Tubes Percutaneous Accessories / Enteral percutaneous feeding tube dressing sets and accessories Basic UDI – 42502737NEN60131s000000RP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
IV Extension Lines Basic UDI - 42502737NIV50212a000000WN	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb / Class IIb implantable (ex-empted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Sets Pressure Basic UDI - 42502737NIV50112a000000VR	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☐ Class IIb / Class IIb implantable (ex-empted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Stopcock Systems Basic UDI - 42502737NIV50512a000000ZD	☐ Class III ☐ Class IIb implantable (non-ex-empted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Syringes / Injectomat®-syringes Basic UDI - 42502737NIV50412a000000YG	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Transfusion Sets Basic UDI – 42502737NIV50312a000000XK	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1: CA# Evidence #2: CA#
Urological tubes / Transfer sets and accessories Basic UDI – 42502737NUR70112a000000B6	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1: CA# Evidence #2: CA#
Transfer Devices (including Extra-Spikes) Basic UDI - 42502737NIV50611s000000BC	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusion Sets Gravity / Secondary infusion lines Basic UDI – 42502737NIV50011s0000005W	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Feeding Syringes_Accessories / Freka® Connect and Cap ENFit™/ProNeo Basic UDI – 42502737NEN60621s0000000VH	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Enteral Feeding Syringe and Accessories / Freka® Connect ENFit/ProNeo Basic UDI – 42502737NEN60612a000000KT	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Check Valves / Back Check Valves Basic UDI – 42502737NIV50912a00000054	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Giving Sets and Accessories Basic UDI –	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
42502737NEN60312a000000H4	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Urine Drainage Tubes / Endoscopy Drainage Tube Basic UDI - 42502737NUR70121s000000LU	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Giving Sets and Accessories Basic UDI – 42502737NEN60321s000000SS	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Adapters Urology / Bladder Syringe Filling Set Care-Lock® Adaptor Spike Adaptor Care-Lock® Injection-site Adaptor Basic UDI - 42502737NUR70121s000000LU 42502737NUR70211s000000M2	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Cannula Systems / Ambix cannulas Basic UDI - 42502737NIV51122a000000XF 42502737NIV51112a000000WQ	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Urine Drainage Bags and System / Nephrostomy Drainage Bag Basic UDI - 42502737NUR70121s000000LU	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Filters Basic UDI - 42502737NIV51012a000000VT	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Percutaneous Tubes Replacement Sets and Accessories / Freka® Buttons and Belly Buttons Basic UDI – 42502737NEN60212b000000GQ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Surgery / Endo Apron PERINEAL DRAPE Basic UDI – 42502737NUR70121s000000LU	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Percutaneous Tubes Replacement Sets and Accessories / Freka® Button Extension set and accessories Basic UDI – 42502737NEN60221s000000RV	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Port Systems (Accessories) / Ambix Introcath® Plus Basic UDI - 42502737NIV51222a000000YC	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Subcutaneous Cannulas / Therastick® Basic UDI –	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
42502737NIV51312a000000YJ	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Caps / Injection, combination and closing caps Basic UDI - 42502737NIV50811s000000D6	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Feeding Products ProNeo / ProNeo Extension and Feeding tubes Basic UDI - 42502737NEN60412a000000HZ	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Enteral Feeding Products ProNeo Basic UDI - 42502737NEN60421s000000TP	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Urological Tubes / Transfer Sets Basic UDI – 42502737NUR70121s000000LU	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G2S 047402 0084 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Agilia SP – Pump Basic UDI - 4052682AIV01012bCF000ACG	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Agilia MRI Guard Basic UDI - 4052682AND33012bCF0000YF	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Agilia ProNeo Basic UDI - 4052682AEN01012aCF000AU8	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Agilia VP – Pump Basic UDI - 4052682AIV02012bCF000ADF	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Amika – Pump & Software Basic UDI - 4052682AEN04012aCF000AX5 4052682AND2201IbSD0000G5	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Amika+ – Pump & Software Basic UDI - 4052682AEN04012aCF000AX5 4052682AND2201IbSD0000G5	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Drop Sensor Basic UDI - 4052682AND37012bHF00006F	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia SP – Pump Basic UDI - 4052682AIV01012bCF000ACG	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia VP – Pump Basic UDI - 4052682AIV02012bCF000ADF	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
LINK+ - Agilia Basic UDI - 4052682AND31012bCF0000WH	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☒ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Ambix Nova – Pump & Software Basic UDI - 4052682AIV02012bCF000ADF, 4052682AND22011IbSD0000G5	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusia Syringe Pump Basic UDI – 4052682AIV02012bCF000ADF	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Infusia Infusion Pump Basic UDI - 4052682AIV02012bCF000ADF	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Agilia Partner Basic UDI - 4052682AND22012bSD000048	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia Partner Basic UDI - 4052682AND22012bSD000048	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Exelia Drop Sensor Basic UDI - 4052682AND37012bHF00006F	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia Combox Basic UDI - 4052682AND36012bCF00003F	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia Therapy Manager Basic UDI - 4052682AND35012bCF00002G	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia Link Basic UDI - 4052682AND31012bCF0000WH	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Exelia ComAdaptor Basic UDI - 4052682AND11012bHF0000W8	☐ Class III ☐ Class IIb implantable (non-ex-empted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Vigilant Software Suite Basic UDI - 4052682AND21012bSD000039	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Vigilant Sentinel Basic UDI – 4052682AND21012bSD000039	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Vigilant Master Med Basic UDI – 4052682AND21012bSD000039	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Agilia Vigilant Drug'Lib Basic UDI – 4052682AND21012bSF00003X	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0083 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
AmiCORE Apheresis System Basic UDI- 081002044ApheresisAndCSZU	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Aurora Plasmapheresis System Basic UDI – 081002044ApheresisAndCSZU	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
COM.TEC Basic UDI - 081002044ApheresisAndCSZU	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class lib / Class lib implantable (exempted) ☐ Class Iia ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
COM.TEC advance Basic UDI - 081002044ApheresisAndCSZU	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class Iia ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Amicus Separator Basic UDI -	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
081002044ApheresisAndCSZU	☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Phelix Photoactivation Device Basic UDI – 081002044Photopheresis3Y	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Amicus ECP Apheresis Kits Basic UDI – 081002044KitApheresisCSVZ	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BioR flex Basic UDI – 081002044Filters002L6	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BioR 02 plus Basic UDI – 081002044Filters002L6	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BioP 10 plus Basic UDI – 081002044Filters002L6	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
BioP flex Basic UDI – 081002044Filters002L6	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
CATSmart Basic UDI – 081002044AutotransfusXD	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
CompoGuard Basic/ Data/ Complete Basic UDI – 081002044CompoGuardSR	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposables for Autotransfusion / Autotransfusion sets and accessories Basic UDI – 081002044KitAutoTransY8	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Disposables for Autotransfusion / Vacuum lines, adapters, cap sets and waste bags for autotransfusion Basic UDI – 081002044KitAutoTrans1s47	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G2S 047402 0085 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
AmiCORE Apheresis Kits Basic UDI –	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
081002044KitApheresisCSVZ	☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Amicus Apheresis Kits – Functionally Closed System and Exchange Kits Basic UDI – 081002044KitApheresisCSVZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Disposables for Apheresis and Cell Separation Basic UDI – 081002044KitApheresisCSVZ	☐ Class III ☐ Class IIb implantable (non-exempted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Plasmacell-C Disposable Sets Basic UDI – 081002044KitApheresisCSVZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
PlasmaLink Bottle Basic UDI- 081002044KitApheresisCSVZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices with measuring function ☐ Class III implantable custom-made device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Transfer Packs (Plasma) Basic UDI – 081002044KitApheresisCSVZ	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Transfer Sets incl. Accessories / Compoflex and Compostop transfer sets and accessories Basic UDI – 081002044TransferBagsGT	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR,



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class III implantable custom-made device		Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Transfer Packs/Sets (Whole Blood) / Compoflex and Compostop transfer sets and accessories Basic UDI – 081002044TransferBagsGT	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Cell Separation System / LOVO Med Cell Processing Disposables Kit with Bag Access Basic UDI - 081002044KitLOVOMedYP	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Blood Donation Systems and Accessories – Dry / Com-poflex - Empty Basic UDI – 081002044BloodDonIIBTC	☐ Class III ☐ Class IIb implantable (non-ex-empted) ☒ Class IIb / Class IIb implantable (ex-empted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	Evidence #2; CA# ☒ Certification as follows: G1 047402 0082 Rev. 00., NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-03-15	713186567 713198383	Initial Issue



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 047402 0082 Rev. 00

Manufacturer:

Fresenius Kabi AG

61346 Bad Homburg
GERMANY

Product Category(ies): **ACTIVE MEDICAL DEVICES (class IIa / IIb)**
Devices for Autotransfusion, Apheresis,
Cell Separation, and Photopheresis;
Accessories for Blood Donation Systems
NON ACTIVE MEDICAL DEVICES (class IIa / IIb)
Transfusion and Transfer Sets incl. Accessories;
Medical Containers; Filters;
Blood Donation Systems and Accessories;
Disposables for Autotransfusion, Apheresis,
Cell Separation, and Photopheresis

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168590

Valid from: 2020-05-19

Valid until: 2024-05-26

Date, 2020-05-19

Christoph Dicks
Head of Certification/Notified Body

T432158.	Compoflex® 4F T&B - 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432162	Compoflex® - 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432163	Compoflex® 4F T&B 49CPD/80SAG-M - PDS-V	46347
T432164	Compoflex® 4F T&B 63CPD/100SAG-M - PDS-V	46347
T432165	Compoflex® - 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432166	Compoflex® 4F T&B 63 ml CPD/100 ml SAG-M - PDS-V	46347
T432167	Compoflex® 4F 63 ml CPD/100 ml SAG-M - PDS-V	46347
T4910	Composelect® 4F 63 ml CPD/100 ml SAGM - WB + PDSV	46347
T4922	Composelect® 5F T&B 63 ml CPD/100 ml SAG-M - RCC - PDS-V	47747
T4924	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
T4926	Composelect® 4F T&B - 63 ml CPD/100 ml SAG-M - RCC + PDS-V	46347
T4927	Composelect® 4F 63 ml CPD/100 ml SAG-M - RCC + PDS-V (F)	46347

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