



**FRESENIUS
KABI**

EG-Konformitätserklärung

EC DECLARATION OF CONFORMITY

Annex II excluding (4) of Directive 93/42/EEC
according to EC-certificate No. G1 047402 0083
issued by Notified Body TÜV Süd Product Service GmbH,
Ridlerstrasse 65, 80339 Munich, Germany, CE0123

Anhang II ausschließlich (4) der Richtlinie 93/42/EWG
entsprechend EG-Zertifikat Nr. G1 047402 0083
ausgestellt durch die Benannte Stelle TÜV Süd Product Service GmbH,
Ridlerstraße 65, 80339 München, Deutschland, CE0123

Enteral Giving Sets and Accessories

(Product name / Produktname)

See attached list / siehe beigefügte Liste
(Article number / Artikelnummer)

Class / Klasse ☒ IIa - ☐ IIb

We / Wir

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.

Hersteller der oben genannten Produkte, erklären hiermit in unserer alleinigen Verantwortung für diese Konformitätserklärung, dass die oben aufgeführten Produkte mit allen relevanten Anforderungen der Direktive 93/42/EWG, geändert durch 2007/47/EG und deren Umsetzung in nationale Gesetze übereinstimmen. Die Produkte erfüllen die Anforderungen des Anhangs I sowie die Anforderungen der weiteren anwendbaren Standards und normativen Dokumente, wie in der anwendbaren technischen Dokumentation aufgeführt. Alle unterstützenden Dokumente werden in den Räumlichkeiten des Herstellers aufbewahrt.

Bad Hersfeld, 29.04.2021

Place and date of issue/
Ort und Datum der Ausstellung

i.v.B. Heyne
Britta Heyne, Regulatory Affairs

Name (printed letters), position and signature of authorized person/
Name (Blockschrift), Position und Unterschrift der autorisierten Person

Valid starting with the original date of the document until product change

Gültig ab Ausstellungsdatum bis Produktänderung

Expiry date of Certificate: 26. May 2024

List of Enteral Giving Sets and Accessories

Article Code	Article Name
7751047	APPLIX Standard Pump Set
7751690	Amika - Pump Set VarioLine
7751691	APPLIX Smart/Vision Pump Set VarioLine
7751692	APPLIX Smart/Vision Pump Set VarioLine, ENLock
7751693	APPLIX Smart/Vision Pump Set VarioLine
7751694	APPLIX Smart/Vision Pump Set VarioLine
7751696	APPLIX Smart/Vision Pump Set VarioLine
7751697	Amika - Pump Set VarioLine, ENLock
7751698	Amika - Pump Set VarioLine (UK)
7751710	APPLIX Smart/Vision Pump Set Bag, ENLock
7751711	APPLIX Smart/Vision Pump Set Bag
7751713	Applix Smart/Vision Pump Set Bag with caps
7751714	APPLIX Smart/Vision Pump Set Bag 1500 ml (UK)
7751715	Amika - Pump Set Bag Set (UK)
7751729	Amika - Pump Set EasyBag
7751731	APPLIX Smart/Vision Pump Set EasyBag
7751732	APPLIX Smart/Vision Pump Set EasyBag, ENLock
7751733	Amika - Pump Set EasyBag, ENLock
7751736	APPLIX Smart/Vision Pump Set Bag mobile
7751737	APPLIX Smart/Vision Pump Set Bag mobile, ENLock
7751738	Amika - Pump Set Bag Set mobile, ENLock
7751743	Amika - Pump Set Bag Set
7751745	Amika - Pump Set Bag Set mobile
7751780	Amika - Pump Set EasyBag mobile (UK)
7751781	APPLIX Smart/Vision Pump Set EasyBag mobil
7751782	APPLIX Smart/Vision Pump Set EasyBag mobile, ENLock
7751783	APPLIX Smart/Vision Pump Set EasyBag mobile (UK)
7751784	Amika - Pump Set EasyBag mobile, ENLock
7751805	Amika - Pump Set EasyBag, ENLock, ENPlus
7751806	Amika - Pump Set EasyBag mobile, ENLock, ENPlus
7751808	Amika - Pump Set VarioLine, ENLock, ENPlus
7751809	Amika - Pump Set Bag Set, ENLock
7751810	Amika - Pump Set EasyBag mobile
7751812	APPLIX Smart/Vision Pump Set EasyBag, ENLock, ENPlus
7751813	APPLIX Smart/Vision Pump Set EasyBag mobile, ENLock, ENPlus
7751814	APPLIX Smart/Vision Pump Set VarioLine Comfort, ENLock, ENPlus
7751815	APPLIX Smart/Vision Pump Set VarioLine, ENLock, ENPlus
7751825	Amika - Pump Set VarioLine Comfort, ENLock, ENPlus
7751826	Amika - Pump Set EasyBag, ENPlus, ENLock
7751827	Amika - Pump Set Two Line EasyBag, ENPlus

List of Enteral Giving Sets and Accessories

Article Code	Article Name
7751828	Amika - Pump Set EasyBag mobile, ENPlus
7751829	Amika - Pump Set Varioline, ENPlus
7751830	Amika - Pump Set Varioline Comfort
7751832	Amika - Pump Set Two Line EasyBag
7751833	Amika - Pump Set EasyBag, step adapter
7751834	Amika - Pump Set EasyBag, step adapter, ENPlus
7751843	Amika - Pump Set EasyBag mobile, step adapter
7751844	Amika - Pump Set EasyBag mobile, step adapter, ENPlus
7751846	APPLIX Smart/Vision Pump Set TwoLine EasyBag, ENPlus
7751847	APPLIX Smart/Vision Pump Set EasyBag, ENPlus
7751848	APPLIX Smart/Vision Pump Set EasyBag mobile, ENPlus
7751849	APPLIX Smart/Vision Pump Set Varioline, ENPlus
7751850	APPLIX Smart/Vision Pump Set EasyBag with cover, ENPlus
7751855	APPLIX Smart/Vision Pump Set EasyBag, step adapter, ENPlus (ELAMA)
7751856	APPLIX Smart/Vision Pump Set EasyBag mobile, step adapter, ENPlus (ELAMA)
7751900	Amika EasyBag, ENPlus, ENFit
7751902	Amika Varioline, ENPlus, ENFit
7751903	Amika TwoLine EasyBag, ENPlus, ENFit
7751904	Amika Varioline Comfort, ENPlus, ENFit
7751905	Amika EasyBag mobile, ENPlus, ENFit
7751906	Amika Bag mobile, ENFit
7751907	Amika Pump Set EasyBag, universal, ENPlus, ENFit
7751908	Amika Pump Set Bag, universal ENFit
7751909	Amika Pump Set Varioline, ENFit universal
7751910	Amika Pump Set TwoLine Easybag, ENFit universal
7751913	Amika Pump Set Bag mobile, ENFit universal
7751914	Amika Bag with cover, ENFit
7751915	Amika Bag mobile with cover, ENFit
7751916	Amika EasyBag mobile with cover, ENFit
7751917	Amika EasyBag with cover, ENFit
7751918	Amika EasyBag non med port with cover, ENFit
7751919	Amika Varioline with cover, ENFit
7751923	Applix Smart/Vision Bag , ENFit
7751924	Applix Smart/Vision Varioline, ENFit
7751925	Applix Smart/Vision TwoLine EasyBag, ENFit
7751926	Applix Smart/Vision Varioline Comfort, ENFit
7751927	Applix Smart/Vision EasyBag mobile, ENFit
7751928	Applix Smart/Vision Bag mobile, ENFit
7751929	Applix Smart/Vision EasyBag with cover, ENFit
7751930	Applix Smart/Vision non med port with cover, ENFit

List of Enteral Giving Sets and Accessories

Article Code	Article Name
7751932	Applix Smart/Vision Varioline with cover, ENFit
7751933	Applix Smart/Vision Bag with cover, ENFit
7751934	Applix Smart/Vision Bag mobile with cover, ENFit
7751935	Applix Smart/Vision TwoLine EasyBag with cover, ENFit
7751943	Applix Smart/Vision Pump Set EasyBag, ENFit universal
7751944	Applix Smart/Vision Pump Set EasyBag with cover, ENFit universal
7751945	Applix Smart/Vision Pump Set Bag, ENFit universal
7751946	Applix Smart/Vision Pump Set Varioline, ENFit universal
7751947	Applix Smart/Vision Pump Set TwoLine EasyBag, ENFit universal
7751948	Applix Smart/Vision Pump Set Varioline Comfort, ENFit universal
7751949	Applix Smart/Vision Pump Set EasyBag mobile, ENFit universal
7751950	Applix Smart/Vision Pump Set Bag mobile, ENFit universal
7751956	Amika Bag, ENFit
7751994	Amika TwoLine EasyBag with cover, ENFit
7751995	Applix Smart/Vision EasyBag, ENFit
7751996	Applix Smart/Vision EasyBag mobile with cover, ENFit
7751998	Amika Pump Set Varioline Comfort, ENPlus, ENFit universal
7751999	Amika Pump Set EasyBag mobile, ENFit universal
7752045	APPLIX Smart/Vision Pump Set Bag mobile (UK)
7752046	Amika - Pump Set Bag Set mobile (UK)
7752051	APPLIX Smart/Vision Pump Set EasyBag with cover
7752053	APPLIX Smart/Vision Pump Set EasyBag (UK)
7752054	Amika - Pump Set EasyBag (UK)
7752055	APPLIX Smart/Vision Pump Set EasyBag
7752085	Amika - Pump Set EasyBag, ENPlus (UK)
7752086	Amika - Pump Set EasyBag, ENPlus (UK)
7752087	Amika - Pump Set EasyBag mobile, ENPlus (UK)
7752088	Amika - Pump Set Varioline, ENPlus (UK)
7752089	Amika Pump Set Two Line EasyBag, ENPlus UK
7752102	APPLIX Smart/Vision Pump Set EasyBag, ENPlus (UK)
7752103	APPLIX Pump Set Easy Bag, ENPlus (UK)
7752104	APPLIX Pump Set EasyBag mobile, ENPlus (UK)
7752105	APPLIX Pump Set Varioline, ENPlus (UK)
7752106	APPLIX Smart/Vision Pump Set Two Line EasyBag, ENPlus (UK)
7752311	APPLIX Smart/Vision Pump Set Y-EasyBag
7752316	APPLIX Smart/Vision Pump Set Y-EasyBag (UK)
7755692	ENContainer Adapter
7980281	Giving Set Extension

List of Enteral Giving Sets and Accessories

Article Code	Article Name
7980282	Giving Set Extention, 100 cm, ENLock
7981411	Freka L Connection
7981421	Freka Verbindung T
7981838	Freka Dual Port Connection, ENFit
7989892	Amika - Pump Set Tubing-connection (Japan)
7989893	APPLIX Pump Set Tubing Connection
7989894	APPLIX Pump Set Tubing Connection
7989951	Freka Dual Port Connector
7989958	Applix Smart/Vision Pump Set DuoLine VarioLine Comfort, ENLock
7989961	APPLIX DuoLine Pump Set Vario Comfort
7989962	APPLIX Smart/Vision Pump Set EasyBag Comfort, ENLock
7989992	Amika - Pump Set Bag (Japan)
7989994	APPLIX Pump Set Bag (Japan)
7751690AP	Amika - Pump Set VarioLine
7751691AP	APPLIX Smart/Vision Pump Set VarioLine (China)
7751691CN	APPLIX Smart/Vision Pump Set VarioLine, China
7751691CNAP	APPLIX Smart/Vision Pump Set VarioLine, China
7751691SA	EQUIPO ENTERAL Equipo Applix Smart Varioline
7751715T	Amika Pump Set Bag, ENFit universal
7751731E	APPLIX Smart/Vision Pump Set EasyBag (ELAMA)
7751731SA	EQUIPO ENTERAL Equipo Applix Smart EasyBag
7751781E	APPLIX Smart/Vision Pump Set EasyBag mobile (ELAMA)
7751830AP	Amika - Pump Set Varioline Comfort
7751943SA	EQUIPO ENTERAL Equipo Applix Smart/Vision EasyBag
7751946SA	EQUIPO ENTERAL Equipo Applix Smart/Vision Varioline
7752085T	Amika Pump Set EasyBag, ENFit universal
775593W	Freka Extention Set, 30 cm
798193W	Freka Extention Set, 30 cm