

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

Percutaneous Tube Replacement 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, 27.05.2020

Place and date of issue/
Ort und Datum der Ausstellung

i.v. B. Heyne
B. 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 Percutaneous Tube Replacement Sets and Accessories

Article Code	Article Name
7750821	Freka GastroTube CH/FR 15
7751239	Freka Belly Button Comfort CH 18, 1,0 cm
7751240	Freka Belly Button Comfort CH 14, 1,0 cm
7751241	Freka Button CH/FR 15, 1.1 cm
7751242	Freka Belly Button Comfort CH 12, 1,0 cm
7751243	Freka Belly Button Comfort CH 16, 1,0 cm
7751244	Freka Belly Button Comfort CH 20, 1,0 cm
7751245	Freka Belly Button Comfort CH 24, 1,0 cm
7751249	Freka Belly Button Comfort CH 16, 1,5 cm
7751250	Freka Belly Button Comfort CH 14, 1,5 cm
7751251	Freka Button CH/FR 15, 1.4 cm
7751252	Freka Belly Button Comfort CH 12, 1,5 cm
7751253	Freka Belly Button Comfort CH 18, 1,5 cm
7751254	Freka Belly Button Comfort CH 20, 1,5 cm
7751255	Freka Belly Button Comfort CH 24, 1,5 cm
7751259	Freka Belly Button Comfort CH 18, 2,0 cm
7751260	Freka Belly Button Comfort CH 14, 2,0 cm
7751261	Freka Button CH/FR 15, 1.7 cm
7751262	Freka Belly Button Comfort CH 12, 2,0 cm
7751263	Freka Belly Button Comfort CH 16, 2,0 cm
7751264	Freka Belly Button Comfort CH 20, 2,0 cm
7751265	Freka Belly Button Comfort CH 24, 2,0 cm
7751269	Freka Belly Button Comfort CH 18, 2,5 cm
7751270	Freka Belly Button Comfort CH 14, 2,5 cm
7751271	Freka Button CH/FR 15, 2.0 cm
7751272	Freka Belly Button Comfort CH 12, 2,5 cm
7751273	Freka Belly Button Comfort CH 16, 2,5 cm
7751274	Freka Belly Button Comfort CH 20, 2,5 cm
7751275	Freka Belly Button Comfort CH 24, 2,5 cm
7751279	Freka Belly Button Comfort CH 18, 3,0 cm
7751280	Freka Belly Button Comfort CH 14, 3,0 cm
7751281	Freka Button CH/FR 15, 2.5 cm
7751282	Freka Belly Button Comfort CH 12, 3,0 cm
7751283	Freka Belly Button Comfort CH 16, 3,0 cm
7751284	Freka Belly Button Comfort CH 20, 3,0 cm
7751285	Freka Belly Button Comfort CH 24, 3,0 cm
7751289	Freka Belly Button Comfort CH 18, 3,5 cm
7751290	Freka Belly Button Comfort CH 14, 3,5 cm

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7751291	Freka Button CH/FR 15, 3.0 cm
7751292	Freka Belly Button Comfort CH 12, 3,5 cm
7751293	Freka Belly Button Comfort CH 16, 3,5 cm
7751294	Freka Belly Button Comfort CH 20, 3,5 cm
7751295	Freka Belly Button Comfort CH 24, 3,5 cm
7751300	Freka Belly Button Comfort CH 14, 4,0 cm
7751301	Freka Button CH/FR 15, 3.5 cm
7751302	Freka Belly Button Comfort CH 12, 4,0 cm
7751303	Freka Belly Button Comfort CH 16, 4,0 cm
7751304	Freka Belly Button Comfort CH 18, 4,0 cm
7751305	Freka Belly Button Comfort CH 20, 4,0 cm
7751306	Freka Belly Button Comfort CH 24, 4,0 cm
7751310	Freka Belly Button Comfort CH 14, 4,5 cm
7751311	Freka Button CH/FR 15, 4.0 cm
7751312	Freka Belly Button Comfort CH 12, 4,5 cm
7751313	Freka Belly Button Comfort CH 16, 4,5 cm
7751314	Freka Belly Button Comfort CH 18, 4,5 cm
7751315	Freka Belly Button Comfort CH 20, 4,5 cm
7751316	Freka Belly Button Comfort CH 24, 4,5 cm
7751320	Freka Belly Button Comfort CH 14, 5,0 cm
7751321	Freka Button CH/FR 15, 4.5 cm
7751322	Freka Belly Button Comfort CH 12, 5,0 cm
7751323	Freka Belly Button Comfort CH 16, 5,0 cm
7751324	Freka Belly Button Comfort CH 18, 5,0 cm
7751325	Freka Belly Button Comfort CH 20, 5,0 cm
7751326	Freka Belly Button Comfort CH 24, 5,0 cm
7751363	Freka Belly Button, Comfort Kit, FR 12 1.0 cm, ENFit
7751364	Freka Belly Button, Comfort Kit, FR 12 1.5 cm, ENFit
7751365	Freka Belly Button, Comfort Kit, FR 12 2.0 cm, ENFit
7751366	Freka Belly Button, Comfort Kit, FR 12 2.5 cm, ENFit
7751367	Freka Belly Button, Comfort Kit, FR 12 3.0 cm, ENFit
7751368	Freka Belly Button, Comfort Kit, FR 12 3.5 cm, ENFit
7751369	Freka Belly Button, Comfort Kit, FR 12 4.0 cm, ENFit
7751370	Freka Belly Button, Comfort Kit, FR 12 4.5 cm, ENFit
7751372	Freka Belly Button, Comfort Kit, FR 12 5.0 cm, ENFit
7751373	Freka Belly Button, Comfort Kit, FR 14 1.0 cm, ENFit
7751374	Freka Belly Button, Comfort Kit, FR 14 1.5 cm, ENFit
7751375	Freka Belly Button, Comfort Kit, FR 14 2.0 cm, ENFit

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Article Code	Article Name
7751376	Freka Belly Button, Comfort Kit, FR 14 2.5 cm, ENFit
7751377	Freka Belly Button, Comfort Kit, FR 14 3.0 cm, ENFit
7751378	Freka Belly Button, Comfort Kit, FR 14 3.5 cm, ENFit
7751379	Freka Belly Button, Comfort Kit, FR 14 4.0 cm, ENFit
7751380	Freka Belly Button, Comfort Kit, FR 14 4.5 cm, ENFit
7751382	Freka Belly Button, Comfort Kit, FR 14 5.0 cm, ENFit
7751383	Freka Belly Button, Comfort Kit, FR 16 1.0 cm, ENFit
7751384	Freka Belly Button, Comfort Kit, FR 16 1.5 cm, ENFit
7751385	Freka Belly Button, Comfort Kit, FR 16 2.0 cm, ENFit
7751386	Freka Belly Button, Comfort Kit, FR 16 2.5 cm, ENFit
7751387	Freka Belly Button, Comfort Kit, FR 16 3.0 cm, ENFit
7751388	Freka Belly Button, Comfort Kit, FR 16 3.5 cm, ENFit
7751389	Freka Belly Button, Comfort Kit, FR 16 4.0 cm, ENFit
7751390	Freka Belly Button, Comfort Kit, FR 16 4.5 cm, ENFit
7751393	Freka Belly Button, Comfort Kit, FR 16 5.0 cm, ENFit
7751394	Freka Belly Button, Comfort Kit, FR 18 1.0 cm, ENFit
7751395	Freka Belly Button, Comfort Kit, FR 18 1.5 cm, ENFit
7751396	Freka Belly Button, Comfort Kit, FR 18 2.0 cm, ENFit
7751397	Freka Belly Button, Comfort Kit, FR 18 2.5 cm, ENFit
7751398	Freka Belly Button, Comfort Kit, FR 18 3.0 cm, ENFit
7751399	Freka Belly Button, Comfort Kit, FR 18 3.5 cm, ENFit
7751400	Freka Belly Button, Comfort Kit, FR 18 4.0 cm, ENFit
7751403	Freka Belly Button, Comfort Kit, FR 18 4.5 cm, ENFit
7751404	Freka Belly Button, Comfort Kit, FR 18 5.0 cm, ENFit
7751405	Freka Belly Button, Comfort Kit, FR 20 1.0 cm, ENFit
7751406	Freka Belly Button, Comfort Kit, FR 20 1.5 cm, ENFit
7751407	Freka Belly Button, Comfort Kit, FR 20 2.0 cm, ENFit
7751408	Freka Belly Button, Comfort Kit, FR 20 2.5 cm, ENFit
7751409	Freka Belly Button, Comfort Kit, FR 20 3.0 cm, ENFit
7751410	Freka Belly Button, Comfort Kit, FR 20 3.5 cm, ENFit
7751413	Freka Belly Button, Comfort Kit, FR 20 4.0 cm, ENFit
7751414	Freka Belly Button, Comfort Kit, FR 20 4.5 cm, ENFit
7751415	Freka Belly Button, Comfort Kit, FR 20 5.0 cm, ENFit
7751416	Freka Belly Button, Comfort Kit, FR 24 1.0 cm, ENFit
7751417	Freka Belly Button, Comfort Kit, FR 24 1.5 cm, ENFit
7751418	Freka Belly Button, Comfort Kit, FR 24 2.0 cm, ENFit
7751419	Freka Belly Button, Comfort Kit, FR 24 2.5 cm, ENFit
7751420	Freka Belly Button, Comfort Kit, FR 24 3.0 cm, ENFit

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Article Code	Article Name
7751422	Freka Belly Button, Comfort Kit, FR 24 3.5 cm, ENFit
7751423	Freka Belly Button, Comfort Kit, FR 24 4.0 cm, ENFit
7751424	Freka Belly Button, Comfort Kit, FR 24 4.5 cm, ENFit
7751425	Freka Belly Button, Comfort Kit, FR 24 5.0 cm, ENFit
7751612	Freka Belly Button Basic, CH 12, 1.0 cm
7751613	Freka Belly Button Basic, CH 12, 1.5 cm
7751614	Freka Belly Button Basic, CH 12, 2.0 cm
7751615	Freka Belly Button Basic, CH 12, 2.5 cm
7751616	Freka Belly Button Basic, CH 12, 3.0 cm
7751617	Freka Belly Button Basic, CH 12, 3.5 cm
7751618	Freka Belly Button Basic, CH 12, 4.0 cm
7751619	Freka Belly Button Basic, CH 12, 4.5 cm
7751620	Freka Belly Button Basic, CH 12, 5.0 cm
7751622	Freka Belly Button Basic, CH 14, 1.0 cm
7751623	Freka Belly Button Basic, CH 14, 1.5 cm
7751624	Freka Belly Button Basic, CH 14, 2.0 cm
7751625	Freka Belly Button Basic, CH 14, 2.5 cm
7751626	Freka Belly Button Basic, CH 14, 3.0 cm
7751627	Freka Belly Button Basic, CH 14, 3.5 cm
7751628	Freka Belly Button Basic, CH 14, 4.0 cm
7751629	Freka Belly Button Basic, CH 14, 4.5 cm
7751630	Freka Belly Button Basic, CH 14, 5.0 cm
7751632	Freka Belly Button Basic, CH 16, 1.0 cm
7751633	Freka Belly Button Basic, CH 16, 1.5 cm
7751634	Freka Belly Button Basic, CH 16, 2.0 cm
7751635	Freka Belly Button Basic, CH 16, 2.5 cm
7751636	Freka Belly Button Basic, CH 16, 3.0 cm
7751637	Freka Belly Button Basic, CH 16, 3.5 cm
7751638	Freka Belly Button Basic, CH 16, 4.0 cm
7751639	Freka Belly Button Basic, CH 16, 4.5 cm
7751640	Freka Belly Button Basic, CH 16, 5.0 cm
7751642	Freka Belly Button Basic, CH 18, 1.0 cm
7751643	Freka Belly Button Basic, CH 18, 1.5 cm
7751644	Freka Belly Button Basic, CH 18, 2.0 cm
7751645	Freka Belly Button Basic, CH 18, 2.5 cm
7751646	Freka Belly Button Basic, CH 18, 3.0 cm
7751647	Freka Belly Button Basic, CH 18, 3.5 cm
7751648	Freka Belly Button Basic, CH 18, 4.0 cm

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Article Code	Article Name
7751649	Freka Belly Button Basic, CH 18, 4.5 cm
7751650	Freka Belly Button Basic, CH 18, 5.0 cm
7751652	Freka Belly Button Basic, CH 20, 1.0 cm
7751653	Freka Belly Button Basic, CH 20, 1.5 cm
7751654	Freka Belly Button Basic, CH 20, 2.0 cm
7751655	Freka Belly Button Basic, CH 20, 2.5 cm
7751656	Freka Belly Button Basic, CH 20, 3.0 cm
7751657	Freka Belly Button Basic, CH 20, 3.5 cm
7751658	Freka Belly Button Basic, CH 20, 4.0 cm
7751659	Freka Belly Button Basic, CH 20, 4.5 cm
7751660	Freka Belly Button Basic, CH 20, 5.0 cm
7751662	Freka Belly Button Basic, CH 24, 1.0 cm
7751663	Freka Belly Button Basic, CH 24, 1.5 cm
7751664	Freka Belly Button Basic, CH 24, 2.0 cm
7751665	Freka Belly Button Basic, CH 24, 2.5 cm
7751666	Freka Belly Button Basic, CH 24, 3.0 cm
7751667	Freka Belly Button Basic, CH 24, 3.5 cm
7751668	Freka Belly Button Basic, CH 24, 4.0 cm
7751669	Freka Belly Button Basic, CH 24, 4.5 cm
7751670	Freka Belly Button Basic, CH 24, 5.0 cm
7755621	Freka GastroTube CH/FR 15 UK
7755648	Freka GastroTube FR 15, ENFit