



EU DECLARATION OF CONFORMITY

Annex IV of Medical Device Regulation (EU) 2017/745

Enteral class I

Refer to attachment
(Product name)

Refer to attachment
(article number, serial number/batch number – if applicable)

Device classification according to Annex VIII, clause 4.2, rule 2 / clause 4.1, rule 1

Class I

We

**Fresenius Kabi AG, Else-Kröner-Str. 1
61352 Bad Homburg, Germany**
Single Registration Number (SRN): DE-MF-000009273

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 the Medical Device Regulation 2017/745 and any other relevant Union legislation that provides for the issuing of this EU Declaration of Conformity. The products comply with the general safety and performance 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.

Ebersburg, 15.04.2024

Dr. Sandra Leipold,
Sr. Manager RA

DocuSigned by:
S. Leipold
Signer Name: Sandra Leipold
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Attachment to EU DECLARATION OF CONFORMITY

Enteral class I

Article Number	Product Name	Basic UDI-DI
7981382	Freka® Repair Set for Freka® PEG FR 9, ENFit	42502737NEN60011x000000RZ
7981383	Freka® Repair Set for Freka® PEG FR 15, ENFit	
7981384	Freka® Repair Set for Freka® PEG FR 20, ENFit	
M90800400	Repair Set for Freka® PEG Pro FR 12	
M90800401	Repair Set for Freka® PEG Pro FR 14	
M90800402	Repair Set for Freka® PEG Pro FR 16	
M90800403	Repair Set for Freka® PEG Pro FR 20	
7981385	Freka® Connector for Freka® PEG FR 9, ENFit	
7981386	Freka® Connector for Freka® PEG FR 15, ENFit	
7981387	Freka® Connector for Freka® PEG FR 20, ENFit	
M90800490	Connector for Freka® PEG Pro FR 12, ENFit	
M90800491	Connector for Freka® PEG Pro FR 14, ENFit	
M90800492	Connector for Freka® PEG Pro FR 16, ENFit	
M90800493	Connector for Freka® PEG Pro FR 20, ENFit	
7751701	Freka® Tube Clamp for Freka® PEG CH/FR 9 and CH/FR 15	
M90800460	Freka® Tube Clamp for FR 12 Freka® Tube Clamp for FR 14	
M90800461	Freka® Tube Clamp for FR 16 Freka® Tube Clamp for FR 20	
7751541	Freka® Fixation Plate for Freka® PEG FR 20	
7903002	Freka® Fixation Plate for Freka® PEG FR 9	
7904002	Freka® Fixation Plate for Freka® PEG FR 15	
M90800430	Fixation Plate for Freka® PEG Pro FR 12	
M90800431	Fixation Plate for Freka® PEG Pro FR 14	
M90800432	Fixation Plate for Freka® PEG Pro FR 16	
M90800433	Fixation Plate for Freka® PEG Pro FR 20	
7981388	Freka® Repair Set for Freka® FCJ, ENFit	
7981389	Freka® Click Adaptor FR 9 for PEG FR 15, ENFit	
7981390	Freka® Click Adaptor FR 12 for PEG FR 20, ENFit	
7981394	Freka® Y-Connector for Freka® PEG FR 15/9, ENFit	
7981396	Freka® Y-Connector for Freka® PEG FR 20/12, ENFit	
M90800352	Freka® Y Connector for PEG FR 15/9, 2xENFit	
M90800354	Freka® Y Connector for PEG FR 20/12, 2xENFit	
M90800374	Freka® Y Connector Freka PEG FR 16/9, ENFit	
M90800375	Freka® Y Connector for PEG FR 16/9, 2xENFit	
7981367	Insert for Freka® GastroTube FR 15, ENFit	

Article Number	Product Name	Basic UDI-DI
7755695	Freka® Universal Funnel Adaptor, ENFit	42502737NEN60011x000000RZ
7981365	Freka® Adaptor LL-ENFit	
7981366	Freka® Connect Adaptor ENFit-LL	
7981376	Freka® ENFit/ENLock Step Adaptor	
7981377	Freka® MediAdaptor ENFit-LL	
7981403	Freka® Cap ENFit / ProNeo	
7981907	Freka® Tape for Tube Fixation	
7981908	ProNeo Plaster	

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