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## Declaration for Systems and Procedure Packs

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### Declaration for systems and procedures packs

(according to Article 22, Regulation (EU) 2017/745)

Freka PEG Pro Hybrid Set, FR 16  
Class of the system or procedure pack: I Ib  
Article code: M90800501

Following devices or products are put together as a system or procedure pack:

Article code	Designation	Declaration of Conformity designation (if applicable)	Class applicable (if applicable)	Applicable Legislation
7601363	Gastropexy Device II	long-term intragastric feeding and gastric decompression	I Ib	MDD
M90800349	Freka PEG Pro Set, FR 16	Percutaneous intragastric long-term feeding and gastric decompression / drainage by gravity	I Ib	MDR

We  
Fresenius Kabi AG  
61346 Bad Homburg, Germany

as system or procedure pack producer declare that

- the mutual compatibility of the devices and, if applicable other products, is verified in accordance with the manufacturers' instructions and these activities were carried out in accordance with the respective manufacturers' instructions;
- we packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
- the whole activity is subjected to appropriate methods of internal monitoring, verification and validation.

For and on behalf of Fresenius Kabi AG,

Date: 01.12.2023

Signed: S. Leipold

Dr. Sandra Leipold  
Senior Manager Regulatory Affairs