

Declaration for Systems and Procedure Packs

Declaration for systems and procedures packs

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

Gastropexy Device II

Class of the system or procedure pack: IIb

Article code: 7601363

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

Article code	Designation	Declaration of Conformity designation (if applicable)	Class (if applicable)
800-000-9923F	Perkutanes Endoskopisches Gastrostomie PEG 15 - II, ENFit (Fixationselement II)	Sterile single use gastrostomy kit	IIa
VN 30 35 00	Thread	Surgical suture	IIb
4501001*	Telaprep (cotton balls)	Telaprep	IIa

*The last digit of the supplier product code can change, for instance, due to changes in the wording on the packaging or the addition of a language in the instruction manual

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,

06-Mar-2026 | 8:00 PM CET

Date:

Signed:

 Signed by:
 Signer Name: Sandra Leipold
 Signing Reason: I approve this document
 Signing Time: 06-Mar-2026 18:00 PM CET
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Dr. Sandra Leipold
 Director Regulatory Affairs