FRESENIUS KABI

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Self DECLARATION OF CONFORMITY

Particular procedure for systems and procedure packs

(Article 12, MDD 93/42/EEC)

Enteral Feeding Tubes percutaneous (Freka® Pexact II FR 15, ENFit)
Class of procedure pack: IIb
Article code: 7601365 (Freka® Pexact II FR 15, ENFit)

Medical Devices used within the procedure pack

Article Code	Designation	DoC Designation	Class
800-001-3827-1	Perkutanes Endoskopisches Gastrostomie PEG 15 – II, ENFit (Ballonkatheter)	Sterile single use gastrostomy kit	IIb
800-001-3827-2	Perkutanes Endoskopisches Gastrostomie PEG 15 – II, ENFit [„T"-PA Scheide (Peel-Away-Schleuse) mit Trokar]	Sterile single use gastrostomy kit	
800-001-3827-3	Perkutanes Endoskopisches Gastrostomie PEG 15 – II, ENFit (Fixationselement II)	Sterile single use gastrostomy kit	
307731	Syringe	Syringe 5ml LS	Im
6603	Scalpel	SWANN-MORTON LIMITED	IIa
VN 40 35 00	Thread	Surgical suture	IIb
4501000	Telaprep (cotton balls)	Telaprep	IIa

We
Fresenius Kabi AG
61346 Bad Homburg, Germany

manufacturer of the procedure pack (article code 7601365), hereby declare under our sole responsibility for this Self 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.
- that the scalpel (REF: 6603) and the cotton balls Telaprep (REF: 4501000) meet the provisions of the Medical Devices Regulation (EU) 2017/745.
- All 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 legal manufacturer.

Postal Address: Fresenius Kabi Deutschland GmbH, 61346 Bad Homburg, Germany
Registered Office: Bad Homburg, Commercial Register Bad Homburg, No. HRB 7367, V.A.T. No. DE 812738852
Managing Directors: Torsten Brandenburger, Andreas Duenkel, Tanja Greve, Dr. Christian Hauer, Andrej Mieth, Steffen Roser, Dr. Michael Schönhofen, Jos Simons
Commerzbank AG, Frankfurt am Main, IBAN: DE39500800000705746500, BIC: DRESDEFFXXX

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We as manufacturer of the procedure pack declare that

(a) the mutual compatibility of the devices is verified in accordance with the instructions and is carried out his operations in accordance with the instructions; and

(b) We packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and

(c) the whole activity is subjected to appropriate methods of internal control and inspection.

On behalf of Fresenius Kabi AG,

S. Leipold

Dr Sandra Leipold
Senior Manager Regulatory Affairs
Fresenius Kabi MedTech – BU INS

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