FRESENIUS KABI

caring for life

Self DECLARATION OF CONFORMITY

Particular procedure for systems and procedure packs
(Article 12, MDD 93/42/EEC)

Enteral Feeding Tubes percutaneous (Gastropexy Device I)
Class of KIT: IIb
Article code: 7601364 (Gastropexy Device I)

Medical Devices used within the KIT

Article Code	Designation	DoC Designation	Class
002-360-0000F	Loop Fixture I (Fixationselement)	Sterile single use gastronomy kit	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 above products, 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. 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.

We as manufacturer 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.

For and on behalf of Fresenius Kabi AG,
19 December 2019

B. Heyne

i.V. Britta Heyne
Senior Manager Regulatory Affairs
BU Devices
Pharmaceuticals and Devices Division

Sitz der Gesellschaft in Bad Homburg
Eingetragen beim Amtsgericht
Bad Homburg HRB 7367

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