Chirurgisches Nahtmaterial
Surgical sutures
Ligatures chirurgicales
Heelkundige hechtingen

www.sutures.be

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25 May 2021

EC-DECLARATION OF CONFORMITY

Manufacturer: **SMI AG - Steinerberg 8 - 4780 ST.VITH - BELGIUM**

We herewith declare under our sole responsibility that the following medical devices conform to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Product Name	Description	Class - Annex IX	GMDN Code
SURGICRYL 910	Sterile Synthetic Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-15 product list	Class III	17471
SURGICRYL PGA	Sterile Synthetic Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-11 product list	Class III	13908
SURGICRYL RAPID	Sterile Synthetic Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-14 product list	Class III	13908
SURGICRYL MONOFILAMENT	Sterile Synthetic Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-13 product list	Class III	16584
SURGICRYL MONOFAST	Sterile Synthetic Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-16 product list	Class III	45814
DACLON NYLON	Sterile Non - Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-09 product list	Class IIb	38000
SUPRAMID	Sterile Non - Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-05 product list	Class IIb	38000
SILK	Sterile Non - Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-08 product list	Class IIb	13910

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POLYPROPYLENE	Sterile Non - Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-05 product list	Class IIb	13909
POLYESTER	Sterile Non - Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-07 product list	Class IIb	13906
STEEL	Sterile Non - Absorbable Suture In atraumatic needle(s) and without needle References: F-E-09-C-10 product list	Class IIb	15971
SURGICAL MESHES	Sterile Surgical Polypropylene Meshes References: F-E-09-C-ZM product list	Class IIb	60300
SURGICAL BLADES	Sterile Surgical Blades References: F-E-09-C-ZB product list	Class IIa	37445
SKIN STAPLER	Sterile Disposable Skin Stapler References: F-E-09-C-ZS product list	Class IIa	46332
SKIN STAPLE REMOVER	Sterile Disposable Skin Staple Remover References: F-E-09-C-ZS product list	Class Is	47192
SKIN MARKER	Sterile Skin Marker References: F-E-09-C-ZSM product list	Class Is	37465

The afore mentioned products are subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, notified body, with identification number 0653.

EC Certificate No: 301011861AD

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

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