Chirurgisches Nahtmaterial
Surgical sutures
Ligatures chirurgicales
Heelkundige hechtingen

www.sutures.be

SMI A.G. · Steinerberg 8 · 4780 St. Vith · Belgium

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St.Vith, 02 February 2018

DECLARATION OF CONFORMITY N° 01

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

hereby declares that the product:

SURGICRYL PGA

Sterile Polyglycolic Acid Absorbable Surgical Suture
In atraumatic needle(s) and without needle

Needle Description		
Characteristics	**Description**	
Needle Types & Codes	Taper point	1/2 circle (HR), 3/8 circle (DR), 5/8 circle (FR), J needle (JR), Straight (GR)
	Reverse cutting	1/2 circle (HS), 3/8 circle (DS), Straight (GS)
	Reverse cutting Easy Pass	3/8 circle (DS)
	Tapercut	1/2 circle (HRT), 3/8 circle (DRT), J needle (JRT)
	Cutting	3/8 circle (NS), 1/2 circle (NH)
	Spatula	1/2, 3/8 or 1/4 circle
	Blunt point	1/2 circle (HRB), 3/8 circle (DRB)
	Without needle	n/a
Number of Needles	1 or 2	
Needle Angle Range	1/4, 3/8, 5/8, 1/2, J, Straight	
Needle Lenght Range	6 mm to 110 mm	
Suture Thread Characteristics		
Suture Color	Violet or Undyed	
Suture Gauze sizes (USP)	6, 5, 4, 3, 2, 1, 0, 2/0, 3/0, 4/0, 5/0, 6/0, 7/0, 8/0, 9/0, 10/0	
Suture Lenght Range	10 cm - 250 cm	
Quantity per Pouch	1-17	
Presentation	Sutures in foil packs	

Has been classified as Class III (Annex IX Rule 8) and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

and is 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 Notified Body,

- **LRQA** (LLOYD'S REGISTER QUALITY ASSURANCE LIMITED)
- 1 Trinity Park Bickenhill Lane, Birmingham B37 7ES
- United Kingdom
- **Notified Body identification number : 0088**

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

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