

Chirurgisches Nahtmaterial Surgical sutures Ligatures chirurgicales Heelkundige hechtingen



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

SMI A.G. Steinerberg 8 4780 St. Vith Belgium Tel.: 00 32 (0)80 227 292 Fax: 00 32 (0)80 226 918 E-mail: info@sutures.be www.sutures.be

St.Vith, November 19th 2014

DECLARATION OF CONFORMITY N° 15

Manufacturer:

SMI AG Steinerberg 8 4780 ST.VITH BELGIUM

hereby declares that the product:

SURGICRYL MONOFILAMENT

Sterile Synthetic Absorbable Suture with or without atraumatic needle References: see annexe F-E-09-13 CE Productlist

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 procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body,

- **SNCH** (SOCIETE NATIONALE DE CERTIFICATION ET D'HOMOLOGATION S.À.R.L.)
- 2a. Kalchesbruck
- L-1852 LUXEMBOURG
- Notified Body number : 0499

Name and function of the responsible person:

André SCHMITZ

Quality Assurance Manager





VAT No.: BE 0432.408.182