

SMI A.G.
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4780 St. Vith
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St.Vith, December 15th 2017

DECLARATION OF CONFORMITY N° 02

Manufacturer: SMI AG
Steinerberg 8
4780 ST.VITH
BELGIUM

hereby declares that the product:

SILK

**Sterile Non - Absorbable Suture
With atraumatic needle and without needle
References: see annexe F-E-09-08 CE Productlist**

Has been classified as Class IIb (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 (excluding section 4) 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

