ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

We hereby certify that the under mentioned manufacturer has established and maintains a full quality assurance system according to the requirements of Directive 93/42/EEC, Annex II (with the exemption of section 4) and its transposition in Greek legislation, for the design, manufacture and final inspection of the products mentioned in this certificate.
The certificate is subject to terms and conditions overleaf.
Any significant changes in design or manufacture may render this certificate invalid.

Certificate Number: 301011861AD

This certificate is issued to replace certificate nr 301011861TN due to the addition of new products.

Manufacturer:	**SMI AG**
Facility:	**STEINERBERG 8, 4780 ST. VITH., BELGIUM.**
Products:	**1. STERILE NON ABSORBABLE SURGICAL SUTURES.** **2. STERILE ABSORBABLE SURGICAL SUTURES.** **3. STERILE SURGICAL BLADES.** **4. STERILE DISPOSABLE SKIN STAPLER.** **5. STERILE DISPOSABLE SKIN STAPLE REMOVER.** **6. STERILE SKIN MARKER.** **7. STERILE SURGICAL POLYPROPYLENE MESHES.**
Brand names:	***As in annex***
Devices Classification:	**1. IIb, 2. III, 3. IIa, 4. IIa, 5. Is, 6. Is, 7. IIb.**
First issue date:	**01/03/2021**
Current issue date:	**25/05/2021**
Valid until:	**24/05/2024**
Audit report:	**200011861**

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

Το Εθνικό Κέντρο Αξιολόγησης της Ποιότητας και Τεχνολογίας στην Υγεία (ΕΚΑΠΤΥ) είναι Κοινοποιημένος Οργανισμός σύμφωνα με την Οδηγία 93/42/ΕΟΚ περί των ιατροτεχνολογικών προϊόντων, με αριθμό αναγνώρισης 0653.
National Evaluation Center of Quality & Technology in Health S.A. (EKAPTY) is a Notified body according to Council Directive 93/42/EEC concerning medical devices, with identification number 0653.

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ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

ANNEX No. 301011861AD CERTIFICATE.

MEDICAL DEVICES	BRAND NAMES
• *Classification IIb* 1. STERILE NON ABSORBABLE SURGICAL SUTURES.	• POLYPROPYLENE • POLYESTER • SILK • NYLON DACLON & SUPRAMID • STEEL
• *Classification III* 2. STERILE ABSORBABLE SURGICAL SUTURES.	• SURGICRYL PGA • SURGICRYL MONOFILAMENT • SURGICRYL RAPID • SURGICRYL 910 • SURGICRYL MONOFAST

TERMS & CONDITIONS

1. For class I sterile products, the certificate covers only the aspects of manufacture concerned with securing and maintaining sterile conditions.
2. For Class I devices with a measuring function the certificate covers only the aspects of manufacture concerned with the conformity of the products with metrological requirements.
3. For class III products an additional Design Examination certificate is required according to the requirements of Annex II 93/42/EEC (section 4).
4. The certificate is valid only for the products and the facilities mentioned.
5. Periodical surveillance as referred in 93/42/EEC will be held in order to verify that the manufacturer maintains and applies the quality system.
6. When meeting with the terms and conditions above, the manufacturer may draw up an EC declaration of conformity and legally affix the CE 0653 mark.

ΠΙΚΡΟΥ - ΜΩΡΑΪΤΑΚΗ ΕΛΕΥΘΕΡΙΑ, Πρόεδρος & Διευθύνουσα Σύμβουλος
PIKROU - MORAITAKI ELEFTHERIA, President & Managing Director

Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/02/19
CL1/V4

Esteemed

SMI AG
Steinerberg 8,
4780 St. Vith
Belgium

Notified Body Confirmation Letter Reference: CERBO0385122

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, NB Name, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SMI AG
Steinerberg 8,
4780 St. Vith
Belgium

SRN Number: BE-MF-000017536

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been

withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile synthetic absorbable surgical suture (54040200215FL)	Class III	N/A	301011861AD 301011861DE4 EKAPTY, NB No. 0653
Sterile synthetic absorbable surgical suture (54040200211FC)	Class III	N/A	301011861AD 301011861DE5 301011861DE2 EKAPTY, NB No. 0653
Sterile synthetic absorbable surgical suture (54040200213FG)	Class III	N/A	301011861AD 301011861DE6 EKAPTY, NB No. 0653
Sterile synthetic absorbable surgical suture (54040200216FN)	Class III	N/A	301011861AD 301011861DE3 EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200205FH)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200207FM)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200208FP)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200209FR)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
STERILE SURGICAL BLADES DISPOSABLE SCALPELS (54040200224FM)	Class IIa	N/A	301011861AD EKAPTY, NB No. 0653

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/19	Rev.0	Initial issue

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111

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www.sutures.be
VAT No.: BE 0432.408.182

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	SMI AG
Manufacturer address and contact details	Steinerberg 8, 4780 St. Vith, Belgium E-Mail: info@sutures.be Tel.: +32 80 227 292
Single Registration Number (SRN)	BE-MF-000017536

Authorised Representative name	Not applicable
Authorised Representative address and contact details	
Single Registration Number (SRN)	

Notified body name	See attached schedule
Notified body number	See attached schedule
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	See attached schedule

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VAT No.: BE 0432.408.182

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above

- Directive Certificate(s) covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
  - ☐ Expires *after* 20 March 2023:
    - ☐ Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made before 26 May 2024 for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- ☐ A QMS in accordance with Article 10(9) MDR is in place.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

SMI AG

St. Vith, 20 February 2024

Andre SCHMITZ

General Manager

E-mail: andre.schmitz@sutures.be

SMI A.G.
Steinerberg 8
4780 St.Vith
Belgium
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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model, catalogue number or Basic UDI-DI under MDR application)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile absorbable surgical suture SURGICRYL 910 Basic UDI-DI (MDR) 54040200215FL	301011861AD 301011861DE4	24/05/2024 Idem	EKAPTY, NB No. 0653	KIWA Cermet Italy S.p.A. (NB No. 0476)	31 December 2027	N/A
Sterile absorbable surgical suture SURGICRYL PGA SURGICRYL RAPID Basic UDI-DI (MDR) 54040200211FC	301011861AD 301011861DE5 301011861DE2	24/05/2024 Idem Idem	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2027	N/A
Sterile absorbable surgical suture SURGICRYL MONOFILAMENT Basic UDI-DI (MDR) 54040200213FG	301011861AD 301011861DE6	24/05/2024 Idem	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2027	N/A
Sterile absorbable surgical suture SURGICRYL MONOFAST Basic UDI-DI (MDR) 54040200216FN	301011861AD 301011861DE3	24/05/2024 idem	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2027	N/A

Sterile non-absorbable surgical sutures POLYPROPYLENE Basic UDI-DI (MDR) 54040200205FH	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
Sterile non-absorbable surgical sutures POLYESTER Basic UDI-DI (MDR) 54040200207FM	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
Sterile non-absorbable surgical sutures SILK Basic UDI-DI (MDR) 54040200208FP	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
Sterile non-absorbable surgical sutures NYLON DACLON SUPRAMID Basic UDI-DI (MDR) 54040200209FR	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
STERILE SURGICAL BLADES DISPOSABLE SCALPELS Basic UDI-DI (MDR) 54040200224FM	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A