SMI A.G.
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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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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Certificate(s) covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.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 will be 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, 28 January 2024

Andre SCHMITZ

General Manager

E-mail: andre.schmitz@sutures.be

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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 or 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 Surgical Polypropylene Meshes Basic UDI-DI (MDR) 54040200222FH	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2027	N/A
Sterile non absorbable surgical sutures STEEL Basic UDI-DI (MDR) 54040200210FA	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
Sterile Disposable Skin Stapler Basic UDI-DI (MDR) 54040200223S34	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
Sterile Disposable Skin Staple Remover Basic UDI-DI (MDR) 54040200223R32	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A
Sterile Skin Marker Basic UDI-DI (MDR) 54040200229FX	301011861AD	24/05/2024	EKAPTY, NB No. 0653	KIWA. NB No. 0476	31 December 2028	N/A