LUX-SUTURES S.A.
22, Gruuss-Strooss
9991 Weiswampach
LUXEMBOURG
info@luxsutures.com
Tel.: 00352-2030-1449

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	LUX-SUTURES S.A.
Manufacturer address and contact details	22, Gruuss-Strooss, 9991 Weiswampach, Luxembourg E-Mail: info@luxsutures.com Tel.: 00352-2030-1449
Single Registration Number (SRN)	LU-MF-000019700

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Certificate(s) covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.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 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:

LUX-SUTURES S.A.

Weiswampach, 23 May 2024

Stephan SCHMITZ

General Manager

E-mail: stephan.schmitz@luxsutures.com

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Luxembourg

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)	**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 sutures LUXCRYL 910	301011860AD 301011860DE1	24/05/2024 Idem	Idem	Idem	31 December 2027	Not applicable
Sterile absorbable surgical sutures LUXCRYL PGA LUXCRYL PGA RAPID	301011860AD 301011860DE2 301011860TN_DE5	24/05/2024 Idem	National Evaluation Center of Quality and Technology in Health S.A. (EKAPTY) NB No.0653	KIWA Cermet Italy S.p.A. NB No. 0476	31 December 2027	Not applicable
Sterile absorbable surgical sutures LUXCRYL PDO	301011860AD 301011860DE3	24/05/2024 Idem	EKAPTY NB No.0653	KIWA NB No. 0476	31 December 2027	Not applicable
Sterile absorbable surgical sutures LUXCRYL MONOFAST	301011860AD 301011860TN_DE4	24/05/2024 Idem	EKAPTY NB No.0653	KIWA NB No. 0476	31 December 2027	Not applicable
Sterile non absorbable surgical sutures LUXYLENE	301011860AD	24/05/2024	EKAPTY NB No.0653	KIWA NB No. 0476	31 December 2028	Not applicable

Sterile non absorbable surgical sutures LUXPET	301011860AD	24/05/2024	EKAPTY NB No.0653	KIWA NB No. 0476	31 December 2028	Not applicable
Sterile non absorbable surgical sutures SILK	301011860AD	24/05/2024	EKAPTY NB No.0653	KIWA NB No. 0476	31 December 2028	Not applicable
Sterile non absorbable surgical sutures LUXAMID & SUPRAMID	301011860AD	24/05/2024	EKAPTY NB No.0653	KIWA NB No. 0476	31 December 2028	Not applicable