

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Lux-Sutures S.A.
Gruuss-Strooss 22
Weiswampach 9991
Luxembourg**

has been assessed against the requirements of Annex II (excluding Section 4) of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ00001135/B
Original Approval: 25 September 2019
Current Certificate: 30 September 2019
Certificate Expiry: 24 September 2022
LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE LRQ 00001135/B SCHEDULE

**In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618**

**Lux-Sutures S.A.
Gruuss-Strooss 22
Weiswampach 9991
Luxembourg**

Scope: Design and Manufacture of sterile Synthetic absorbable Sutures and non-absorbable Sutures with or without atraumatic Stainless steel needles

Class IIb

Sterile Non-absorbable Stainless Steel Sutures
Sterile Non-absorbable Silk Sutures
Sterile Non-absorbable Polyamide-Nylon Sutures – LUXAMID
Sterile Non-absorbable Polypropylene Sutures - LUXYLENE

Class III

LUXCRYL 910

EC Design Examination Certificate

0088/00001135/00426

Schedule Issue: 02

Date of Schedule Issue: 30 September 2019

LRQA Notified Body Number 0088



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