

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

10 May 2021

DECLARATION OF CONFORMITY

Manufacturer: LUX-SUTURES S.A.
22, Gruuss-Strooss, 9991 Weiswampach
LUXEMBOURG

We herewith declare under our sole responsibility that the product:

SURGICAL BLADES

Sterile surgical blades
GMDN code: 37445

SURGICAL BLADES STERILE	REF	UNIT
SURGICAL BLADES STERILES N° 10	LUSB10	100 Pc.
SURGICAL BLADES STERILES N° 11	LUSB11	100 Pc.
SURGICAL BLADES STERILES N° 12	LUSB12	100 Pc.
SURGICAL BLADES STERILES N° 12d	LUSB12D	100Pc.
SURGICAL BLADES STERILES N° 15	LUSB15	100 Pc.
SURGICAL BLADES STERILES N° 15c	LUSB15C	100 Pc.
SURGICAL BLADES STERILES N° 18	LUSB18	100 Pc.
SURGICAL BLADES STERILES N° 20	LUSB20	100 Pc.
SURGICAL BLADES STERILES N° 21	LUSB21	100 Pc.
SURGICAL BLADES STERILES N° 22	LUSB22	100 Pc.
SURGICAL BLADES STERILES N° 23	LUSB23	100 Pc.
SURGICAL BLADES STERILES N° 24	LUSB24	100 Pc.
SURGICAL BLADES STERILES N° 25	LUSB25	100 Pc.
STITCH CUTTER	LUSC	100 Pc.
SURGICAL BLADES STERILES N° 10	LUSD10	10 Pc.
SURGICAL BLADES STERILES N° 11	LUSD11	10 Pc.
SURGICAL BLADES STERILES N° 12	LUSD12	10 Pc.
SURGICAL BLADES STERILES N° 15	LUSD15	10 Pc.
SURGICAL BLADES STERILES N° 20	LUSD20	10 Pc.
SURGICAL BLADES STERILES N° 21	LUSD21	10 Pc.
SURGICAL BLADES STERILES N° 22	LUSD22	10 Pc.
SURGICAL BLADES STERILES N° 23	LUSD23	10 Pc.
SURGICAL BLADES STERILES N° 24	LUSD24	10 Pc.

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is a medical device and has been classified as Class IIa (Annex IX Rule 6). It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC

It is subject to the conformity assessment procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of the National Evaluation Center of Quality and Technology in Health, EKAPTY, Notified body, with identification number 0653.

Name and function of the responsible person:

Nico WEBER
QA & RA Manager

A handwritten signature in blue ink, appearing to read "Nico Weber", written over a horizontal line.