



EC CERTIFICATE

TELIC, S.A.U.

Polígono Industrial Can Barri, C/ Molí d'en Barri, 7-9
08415 Bigues, Barcelona, Spain

Production Quality Assurance System Approval Certificate

Annex V, section 3 of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:

Manufacture of General and Vascular Surgery Devices

Device Classification:
Class IIa

G/UMDN Code:
61916

Device Descriptions:

A sterile, nonimplantable cord intended to be used during a surgical procedure to assist a surgeon to identify, retract and occlude blood vessels, tendons and nerves. It is constructed of synthetic polymer and is typically coloured to facilitate visualization. This is a single-use device.

Model Type:

Refer to Attachment 1

We hereby declare that an examination of the production quality assurance system has been carried out per report 11801655, following the requirements of the national legislation to which the undersigned is subject, transposing Annex V of Council Directive 93/42/EEC on Medical Devices. We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC. Annex V, Section 4. For Class IIb & III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex III is required. This certificate is issued with 1 attachment listing model numbers covered by this certificate.

File Number A17128
Certificate No. 736.170827

Cycle Start Date 27 August 2017
Effective Date 27 August 2017
Expiry Date 26 August 2022

Authorised by

Deborah Stubbs
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Surgical vessel loop	Surgical vessel loop	405305	Ila	61916
		402509	Ila	61916
		402505	Ila	61916
		402503	Ila	61916
		402501	Ila	61916
		401909	Ila	61916
		401905	Ila	61916
		401903	Ila	61916
		401901	Ila	61916
		400709	Ila	61916

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