

EC DECLARATION OF CONFORMITY

Manufacturer's Name: XcellLance Medical Technologies Pvt. Ltd.
Manufacturer's Address: Plot No. W-239, TTC Industrial Area, Rabale MIDC Rd.,
MIDC Industrial Area, Rabale, Navi Mumbai,
Maharashtra 400701, INDIA.
Device: Electrosurgical unit (Diathermy) for cutting & coagulation of body tissues

Declare under our sole responsibility that the products described below are in conformity with the applicable provisions of Council Directive 93/42/EEC Annex II excluding Section 4 concerning medical devices and Essential Requirements set out in Annex-I of the same Directive.

Sr. No.	Product Family	Products Variants/ Models	Product Code	Device Classification (as per Annexure IX, Rule 9)
Basic Model				
1.	Shalya Easy	Shalya LX	E011	I Ib
		Shalya Easy	E015	I Ib
		Shalya Easy+	E021	I Ib
		Shalya Easy+V	E024	I Ib
		Shalya VesSeal	E035	I Ib
Advanced Model				
2.	Shalya TURoSeal	Shalya TURoSeal	E042	I Ib
		Shalya MX	E034	I Ib
		Shalya DX	E028	I Ib
3.	Shalya Vista	Shalya Vista	E065	I Ib
		Shalya Penta	E085	I Ib
4.	Shalya Sigma+	Shalya Sigma	E051	I Ib
		Shalya Sigma+	E055	I Ib
		Shalya Sigma+V	E056	I Ib

The object of the declaration described above is in conformity with the relevant harmonization legislation as follows:

(A) Directive(s)_Date of last revision: i) 93/42/EEC (MD) (2007-09-21)
ii) 2011/65/EU (RoHS) (2015-11-03)

(B) Conformity Assessment Procedure: Annex II (Full Quality Assurance System) of MDD 93/42/EEC

(C) Relevant Harmonized Standards

Sr. No.	Standard Ref. No.	Description of the Standard
1.	ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes
2.	IEC 60601-1:2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3.	IEC 60601-1-2:2007	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
4.	IEC 60601-2-2:2009	Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories
5.	EN 1041:2008	Information supplied by the manufacturer of medical devices
6.	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
7.	EN IEC 62304: 2006	Medical device software -- Software life cycle processes

Name & Address of the Notified Body:

SGS Belgium NV
Noorderlaan 87,
BE-2030 Antwerpen,
Country : Belgium
CE 1639
Issue Date. 16/12/2019

EC Authorized Representatives for Regulatory Affairs

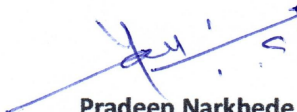
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XcellLance Medical Technology Pvt. Ltd.

CE Certificate No. : IN19/818843701

Date: 16/12/2019

Authorized Signatory


Pradeep Narkhede
(Managing Director)