EC DECLARATION OF CONFORMITY

Manufacturer's Name: **XcelLance 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	IIb
		Shalya Easy	E015	IIb
		Shalya Easy+	E021	IIb
		Shalya Easy+V	E024	IIb
		Shalya VesSeal	E035	IIb
Advanced Model				
2.	Shalya TURoSeal	Shalya TURoSeal	E042	IIb
		Shalya MX	E034	IIb
		Shalya DX	E028	IIb
3.	Shalya Vista	Shalya Vista	E065	IIb
		Shalya Penta	E085	IIb
4.	Shalya Sigma+	Shalya Sigma	E051	IIb
		Shalya Sigma+	E055	IIb
		Shalya Sigma+V	E056	IIb

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

CE US FDA ISO 13485

XcelLance Medical Technologies Pvt. Ltd.
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CIN: U33119MH2008PTC177419

(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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XcelLance Medical Technology Pvt. Ltd.
CE Certificate No. : IN19/818843701

Date: 16/12/2019

Authorized Signatory

Pradeep Narkhede
(Managing Director)