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:	**Operating Room (Surgical) Light for visible illumination of surgical area** **GMDN Number: 37332**

Declare under our sole responsibility that the products described below are in conformity with the applicable provisions of Council Directive 93/42/EEC concerning medical devices and Essential Requirements.

Sr. No.	Product Family	Products Variants/ Models	Device Classification (as per *Annexure IX*, Rule 1)
1.	Shalya iLUX	**Single Dome:** iLUX 10 M/W/O iLUX 20 M/W/O/C iLUX 40 M/W/O/C iLUX 12 M/W/O	Class I
		Multi Dome: iLUX 10-10 O iLUX 10-12 O iLUX 10-20 O/C/D iLUX 10-40 O/C/D iLUX 20-20 O/C/D iLUX 20-40 O/C/D iLUX 40-40 O/C/D iLUX 20-20-20 O/C/D iLUX 20-40-40 O/C/D iLUX 40-40-40 O/C/D iLUX 10-20-20 O/C/D	

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 (MDD) (2007-09-21)
ii) 2011/65/EU (RoHS) (2015-11-03)

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Date: 2022.05.11 08:49:29 EEST
Reason: MoldSign Signature
Location: Moldova

(B) Refer Test Reports:

i)IEC 60601-1:2005 + AMD:2012 (ITC/TEST/NN/1609/05)
ii)IEC 60601-1-2:2014 (TR/ETL/188/16-17)
iii)IEC 60601-2-41:2009 (ITC/TEST/NN/1609/05)

(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+AMD1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3.	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4.	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
5.	EN IEC 62304: 2006	Medical device software - Software life cycle processes
6.	IEC 62336-1: 2015	Application of Usability Engineering to Medical Devices
7.	IEC 60601-2-41:2009	Medical electrical equipment - Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
8.	IEC 60364-7-710	Electrical installation of buildings – Part 7-710: Requirements for special installations or locations – Medical locations
9.	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices

EC Authorized Representatives for Regulatory Affairs:
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Date: 10/12/2020

Authorized Signatory

Pradip Narkhede
(Managing Director)

CE