

Technical File

LightForce® Therapy Lasers

Declaration of Conformity (EU)

Rec No.: PDPROJ-2-541

Version: 1

PRODUCT IDENTIFICATION	
Device Family	Device trade names
LightForce Therapy Lasers	LIghtForce FXi
	LightForce EXPi
	LightForce XPi
	LightForce XLi

MANUFACTURER		
Name of company	Address	Representative
LiteCure, LLC	101 Lukens Dr, Suite A New Castle, DE 19720 USA	Quality & Regulatory Director

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Contact
Emergo Europe	Prinsessegracht 20	P: +31 (0)70 345 85 70
	2514 AP The Hague	F: +31 (0) 70 346 72 99
	The Netherlands	, ,

REGISTRATION INFORMATION		
Notified Body and ID #	Marking	CE certificate number
BSI (NL) – 2797	C E 2797	CE 542523

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa	Annex II of MDD	IEC 60601-1:2005+A1:2012
Rule 9	93/42/EEC Council	IEC 60601-1-2:2015
	Directive	IEC 60601-1-6:2010+A1:2013
		IEC 60601-2-22:2007+A1:2013
		IEC 60825-1:2014

Litecure, LLC declares that the above-mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and amendment 2007/47/EC as transposed in the national laws of the Member States.

Eric Rock	Circle and
Quality and Regulatory Representative Print Name	Sign
New Castle, Delaware, USA	25 MAY 2021
Placa	Data

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