DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 as amended by Directive 2007/47/EC CONCERNING MEDICAL DEVICES

Shenzhen Raycome Health Technology Co., Ltd.
No.501, Block B, Xinfeng Building/ Yangguang community, Xili Street, Nanshan District,Shenzhen, 518055, China

Medical Device: Laser Pain-Relief Instrument

Models: RG-300IB, LLT-500

Classification - Annex IX: class IIa, rule 10

Conformity assessment Route: Annex II excluding 4

We, Shenzhen Raycome Health Technology Co., Ltd., herewith declare that the stated medical devices meet the transposition into national law, the provisions of council directive 93/42/EEC of 14 June 1993 concerning medical devices, and the amendments by council directive 2007/47/EEC of 5 September 2007.

All supporting documentation is retained at the premises of the manufacturer.

Standard:

All applicable harmonized Standards (published in the Official Journal of the European Communities)

EN ISO 13485: 2016/AC: 2018	EN ISO 14971: 2012	EN 60601-1:2006/A1: 2013	EN 60601-1-2: 2015
EN 60601-1-6: 2010	EN 62304: 2006/AC:2008	EN 60601-1-11: 2010	EN 62366: 2008
EN ISO 10993-5: 2009	EN ISO 10993-1:2009+AC:2010	EN ISO 10993-10:2013	EN ISO 15223-1:2016
EN 1041:2008	EN 60601-2-22:2013	EN 60825-1:2007	MEDDEV. 2.7.1 Rev.4: 2016
MEDDEV 2.12-2 Rev 2: 2012			

Notified Body:
MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
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20355 Hamburg
Germany
Notified Body number: 0482

CE Certificate No.: 7120GB410201209A

UK responsible person: SHARE INFO LTD

Add: 14, Castle Walk, London-Stansted, CM24 8LY, United Kingdom

Place, Date of Declaration: Shenzhen, China

Signature:

Name: Zhao Peng

Position: Manager Representative