EC CERTIFICATE

DMC Importação e Exportação de Equipamentos LTDA

Rua Sebastião de Moraes, 831
São Carlos, São Paulo 13562-030 BRAZIL

Full Quality Assurance System
Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:
Design and manufacture of Laser Therapy Equipment

Device Classifications:
Class IIa

Device Descriptions and Model Type:
Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC. Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number	A16590	Cycle Start Date	May 8, 2018
Certificate Number	1665.180508	Effective Date	May 8, 2018
Initial Issue Date	May 8, 2018	Expiry Date	May 7, 2023

Authorised by

Paul Daysh
Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Therapy Equipment	Laser Therapy	Therapy XT	Class IIa	UMDN 18220
		Therapy Plus	Class IIa	UMDN 18220
		Therapy EC	Class IIa	UMDN 18220
		Therapy ILIB	Class IIa	UMDN 18220

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