

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

# EC Certificate - Full Quality Assurance System No. 17 0187 QS/NB

The quality system of manufacturer

#### Medical Quant Ltd.

14 Hataash St., Kfar-Saba 4425144, Israel

has been certified as meeting the requirements of

#### Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

#### General therapeutic low-intensity laser, battery-powered

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2017-04-28 Valid until: 2022-04-27 First Issued: 2017-04-28

Revision:

Date: 2017-04-28

NOTIFIED BODY 1070

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023

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#### Notified Body 1023 INSTITUTE FOR TESTING AND CERTIFICATION, Inc., třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

### Annex to EC Certificate No. 17 0187 QS/NB

issued for manufacturer:

Medical Quant Ltd. 14 Hataash St., Kfar-Saba 4425144, Israel

#### Product(s):

**Handy Cure s'** Name:

Handy Cure s' Trade name(s):

Model(s):

lla Class:

60410 **GMDN:** 

#### Facility(ies):

Medical Quant Ltd.

14 Hataash St., Kfar-Saba 4425144, Israel

RNDr. Radomír Čevelík Representative of the Notified Body No. 1023

Date: 2017-04-28 Revision: -



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#### **Certificate History:**

Revision	Date	Reference Number	Action
	2017-04-28	803602539	Certification



Date: 2017-04-28

Revision: -

RNDr. Radomír Čevelík Representative of the Notified Body No. 1023