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

EC Certificate - Production Quality Assurance
No. 18 0462 QS/NB

The quality system of manufacturer

MEREBIT s.r.o.

Tyršova 942, 69123 Pohořelice, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

for the following product category(ies):

Hyperhidrosis Iontophoresis System

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

Valid from: 2018-10-12
Valid until: 2023-10-11
First Issued: 2018-10-12
Revision: -

Date: 2018-10-12

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

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

Annex to EC Certificate No. 18 0462 QS/NB

issued for manufacturer:

MEREBIT s.r.o.
Tyršova 942, 69123 Pohořelice, Czech Republic

Product(s):

Name:	**OZO-OZO Ionto-MINI**
Trade name(s):	OZO-OZO Ionto-MINI
Model(s):	-
Class:	IIa
GMDN:	174221

Facility(ies):

MEREBIT s.r.o. – legal address
Tyršova 942, 69123 Pohořelice, Czech Republic

MEREBIT s.r.o. – manufacturing site
Karásek 2245/1f, 62100 Brno – Řečkovice, Czech Republic

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Certificate History:

Revision	Date	Reference Number	Action
	2018-10-12	803602347	Certification

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