ELAMED All for your health. Health for you.

25 Yanin st., Yelatma, Ryazan region, 391351, Russia
Tel./fax: +007 49131/2-04-57, 2-21-09, 4-38-29. E-mail: admin@elamed.com; www.elamed.com
Fabricator: YELATMA INSTRUMENT-MAKING Enterprise

DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42 EEC FOR MEDICAL PRODUCTS

Yelatma, Oct 23, 2019

"Yelatma Instrument Making Enterprise", JSC
25 Yanina Str., Yelatma, Kasimov district,
Ryazan region 391351 Russia
tel./ fax: +7 (4912) 503-023

Products of class IIa:
- Tonometer, ophthalmic EASYTON,
- Thermal vibromassage magnetic therapy ULP-01 "ELAT",
- Thermal therapy UTL-01"ELAT",
- Magnetoacoustic therapy MAGOFON-01,
- Magnetotherapy ALMAG-01, ALMAG-02.

meet the requirements of MDD 93\42\EEC.

The Enterprise Quality System meets the requirements both of harmonized standard EN ISO 13485:2016 and MDD 93\42\EEC Annex II.

JSC «Yelatma Instrument Making Enterprise» is certified by TUV NORD CERT GmbH Certification Body, Langemarckstrasse 20, D-45141 Essen, ID. No.0044.

Issued certificate No. 44 232 117836, period of validity: from 28.09.2019 to 26.05.2024
Issued certificate No. 44 221 117836, period of validity: from 28.09.2019 to 27.09.2022

The present declaration confirms that products manufactured according to the technical documentation in compliance with Annex VII 93/42 EEC conform to essential requirements of MDD 93/42 EEC Annex I and the Reference and the relevant standard IEC 60601-1:2005/A1:2012 in accordance with Commission communication in the framework of the implementation of the Council Directive 93/ 42/EEC concerning medical devices and are entitled to have an CE mark.

Authorized Representative in EC Countries:
K. Meng, MK TOURISTENBETREUUNG & MEDTECHNIK
Theodor-Heuss St. 76 Cologne 51149 Germany
tel: + 49 (02203) 965377, fax. +49 (02203) 32949
e-mail: mktour@mktour.com
www.medtechnik.biz

Director of the Scientific and Technical Center: 

Mr. Eduard Klevtsov