EC-Declaration of Conformity for Medical Devices

We, the manufacturer	CardioMedTreadmills SA Medical Technology SA Lakkoma GR-6380 Nea Kallikratia
declare under our sole responsibility that the medical device	Medical Treadmill (Stress Test) CMT

meets all the provisions of the directive 93/42/EEC and the harmonised standards which apply to it.

Classification	Class I *According to the directive 93/42/EEC, AnnexV*
Conformity Assessment Procedure	*according to the directive 93/42/EEC, annex V* *EN 60601-1(2010)* Medical electrical Equipment General Requiremnets for Safety and essential performance *EN 60601-1-2(2010)* Medical electrical Equipment Electromagnetic Compatibility - Requiremnets and Tests *EN ISO 14971 (2012) Risk Analysis Management (RMF)* *EN ISO 957-1(2010)* Stationary training equipment - Part 1: General safety requirements and test methods *EN ISO 957-6(2014) Stationary training equipment - Part 6: Treamills* requirements and test methods

Lakkoma, 12/11/15

ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΗ Α.Ε
ΒΙΟΜΗΧΑΝΙΑ ΙΑΤΡΙΚΟΥ ΕΞΟΠΛΙΣΜΟΥ
ΛΑΚΚΩΜΑ ΧΑΛΚΙΔΙΚΗΣ 63080
ΑΦΜ: 099336055 - ΔΟΥ: Ν. ΜΟΥΔΑΝΙΩΝ
Α.Μ.Α.Ε. 57718 / 61 / Β / 04 / 14

Anastasios Tsiaousidis

President

CERTIFICATE

TÜV AUSTRIA

Management System as per EN ISO 9001 : 2008

In accordance with TÜV AUSTRIA procedures, it is hereby certified that

MEDICAL TECHNOLOGY S.A.
GR-630 80 LAKKOMA, HALKIDIKI, GREECE

Applies a Quality Management System in line with the above Standard for the following Scope

DESIGN, PRODUCTION, TRADING, DISTRIBUTION AND TECHNICAL SUPPORT OF:

- **MEDICAL DEVICES TREADMILLS FOR STRESS TEST AND PHYSIOTHERAPY**
- **TREADMILLS FOR ATHLETICS.**

Certificate Registration No.: **010150376**

Valid until: 2018-09-15

Certification Body
at TÜV AUSTRIA

Athens, 2015-12-29

This certification was conducted in accordance with TÜV AUSTRIA auditing and certification procedures and is subject to regular surveillance audits.

TÜV AUSTRIA HELLAS
429, Mesogeion Ave.
GR-153 43 Athens, Greece
www.tuvaustriahellas.gr

MS Certification
No. of Certificate 236

CePRK416_A4e

TÜV AUSTRIA
GROUP

HELLENIC REPUBLIC
MINISTRY OF HEALTH
NATIONAL ORGANIZATION OF MEDICINES
Mesogeion 284, 155 62 Cholargos
Website : www.eof.gr
Address: Product Assessment
Department: Health Material Assessment
Information : B. Safra
Tel. Number : 2132040324

Cholargos, 11-11-2015
Num. Prot.: 65811

To: **Iatrotechnologiki S.A.**
LAKKOMA,PC 63080
N. KALLIKRATEIA

CERTIFICATE REENTLISTMENT IN MANUFACTURER RECORD
FOR MEDICAL DEVICES CATEGORY I

Considering that:

1. The common ministry determination ΔΥ8δ/Γ.Π.οικ.130648/30-8-209/ ΦΕΚ Β/ 2198/2-10-2009 « Harmonization the Hellenic Legislation with the Guidance 93/42/ΕΟΚ/14-6-1993 from the Council European Union»
   As applicable today.
2. The **65811/05-10-2015** application form for reenlistment in MANUFACTURER RECORD FOR MEDICAL DEVICES and the attachment to it appropriate document
3. The application form **84351/10/14-03-2011** prior certificate listing in the MANUAFCTURER RECORD FOR MEDICAL DEVICES from NATIONAL ORGANAZATION OF MEDICINES with closing date 02-11-2015

CERTIFY

The reenlistment in the MANUAFCTURER RECORD FOR MEDICAL DEVICES from NATIONAL ORGANAZATION OF MEDICINES, according to the defined in the article 14 ΚΥΑ ΔΥ8δ/Γ.Π.οικ.130648/30-8-209/ ΦΕΚ Β/ 2198/2-10-2009, with the following identify:

MANUFACTURER	IATROTECHNOLOGIKI S.A.
ADDRESS	LAKKOMA, 63080, N. KALLIKRATEIA
TEL. NUMBER	0030 2399020278
FAX	0030 2399020278
WEBSITE	WWW.WOLFMEDICA.GR
EMAIL ADRESS	tsiguepe@otenet.gr

RECORD NUMBER (*): I 611 11 2020

(*) The record number consist from description (I= category I or ΕΠ= from order), the code and the expiry date of your listing (11/2020).

PRODUCTS CATEGORY I

A/A	PRODUCT	GMDN CODE
1	STRESS TEST TREADMILL	36679
2	STREES TEST TABLE	17895
3	HOSPITAL TYPE BED 4 PART A.STANDARD ELEVATION MECHANICAL MOVEMENT OF THE BACK AND LEGS B. ELECTRICAL ELEVATION ELECTRICAL MOVEMENT OF THE BACK AND LEGS C.STANDARD ELEVATION ELECTRICAL MOVEMENT OF THE BACK AND LEGS	 34873 34870 34870
4	SIMPLE EXAMINATION TABLE WITH MECHANICAL MOVEMENT OF THE BACK	38458
5	EXAMINATION TABLE 2/3 PARTS ELECTRICAL MOVEMENT	34134
6	TILT TABLE (ELECTRICAL)	37201
7	MULTISECTION ELECTRICAL EXAMINATION TABLE (DREINAGE)	42577
8	GYNECOLOGICAL EXAMINATION CHAIR WITH ELECTRICAL MOVEMENTS	13960
9	INFUSION HOLDER HIGH ADJUSTED	40509
10	HOSPITAL NIGHTSTAND	31220

The above products from your company, in their disposal in the market, have to abut the label CE (article 17 from the common ministry determination ΔΥ8δ/Γ.Π.οικ.130648/30-8-209/ ΦΕΚ Β/ 2198/2-10-2009).
In case unjustified installation of the label CE applies the article 18 from the same ministry decision.

The manufacturer, in according to the Annex VII an. 2, the common ministry determination ΔΥ8δ/Γ.Π.οικ.130648/30-8-209/ ΦΕΚ Β/ 2198/2-10-2009, compiles technical file with the technical documentation which describes in the part 3 from the same Annex. This file with the statement of compliance owe to have available the NATIONAL ORGANAZATION OF MEDICINES, for inspection, at least five years from the last manufactured product.

The listing in the record for MANUAFCTURER RECORD FOR MEDICAL DEVICES category I, happens with the appliance of article 14 of the ministry determination ΔΥ8δ/Γ.Π.οικ.130648/30-8-209/ ΦΕΚ Β/ 2198/2-10-2009, based on the statement of compliance filed and constituted any approval of quality, safety and effectiveness of the product.

Your listing validates until **02-11-2020** (expiry date for the primary certificate listing/ reenlistment with five years validation).
Two (2) months before the expiry of validation from the present document and if you are still manufacturing the above products, you have to do the reenlistment applied for the appropriate document to the NATIONAL ORGANAZATION OF MEDICINES. Every change in the elements of the certification must be assert to the NATIONAL ORGANAZATION OF MEDICINES with the submission of τηε application form for modification or/and supplementation the previous.

The OVERSEER

STAMP **MANAGER OF Product Assessment**

M. ORFANOY