medical® leather

a healthy focus on feet

Product Specific Information Document

Product name:	**Infrarood thermometer**
Item code:	IR 10
Barcode:	see packaging
CE Marking:	see packaging
MDR Risk Classification:	Riskclass I
Product summary:	Infrarood thermometer
Size / Contents product:	141 x 45 x 37 mm
Packaging size:	one piece
Packaging unit:	per piece
Color:	white and purple
Thickness:	N/A
Shorevalue:	N/A
Implementation:	N/A
Storage advise:	N/A
Maintenance advise:	Multiple use
Sterilasation advise:	N/A
Manufacturing date:	N/A
Shelf life:	N/A

Postbus 95, 5140 AB Waalwijk • Zanddonkweg 6, 5144 NX Waalwijk • The Netherlands
Telefoon +31 (0)416 37 69 87 • **Fax** +31(0)416 37 56 02 • **E-mail** info@medical-leather.nl •
Website www.medical- leather.nl **Rabobank** 1308.95.377 • **BIC Code** RABONL2U • **IBAN nr.** NL63 RABO 0130 8953 77 •
KVK 18124129 • **BTW nr.** NL8145 15 745 B01

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DECLARATION OF CONFORMITY

The undersigned
C.J. Maas – Leder LEFA BV. / Medical Leather
In reference
To the REACH Regulation 1907/2006/CE
Concerning the Registration, Evaluation, Authorization
And the restriction of chemical substances

DECLARES THAT

- Our company purchases and sells foam sheets through the transformation of polymers, mineral fillers, pigments and chemicals. Therefore, as a user, our company is not bound to any registration
- According to the REACH Regulation polymers are exempted from registration (article 2) as well as most of the raw materials used.
- Through the raw material suppliers and sheet suppliers, we were able to ascertain compliance with the REACH legislation. In fact, the chemical manufacturers, where provided, have taken steps as for regular registration.
- With regard to the presence of hazardous substances (SVHC) mentioned in **the last list published by ECHA on 25/06/2020** we declare that our products, after curing, as supplied by us, has no hint of SVHC in a concentration above the threshold limit of 0.1%..

Pieve del Cairo, 22/07/2020

REACH Responsible
Pieter Maas

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Certificate CN11/30546

The management system of

Famidoc Technology Co., Ltd.

No. 212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town,
Dongguan, Guangdong Province, 523853, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and distribution of Infrared Thermometers, Upper Arm Blood Pressure Monitor, Digital Clinical Thermometers, Ultrasonic Nebulizers on Conscious Patients, Electrical Stimulators

This certificate is valid from 20 May 2020 until 19 May 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2023
Issue 9. Certified since 19 May 2011

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

UKAS MANAGEMENT SYSTEMS
0005

HC SGS 13485 2016 0118

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: FAMIDOC Technology Co., Ltd.
No.212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town, Dongguan 523853,Guangdong Province, China.

MEDICAL DEVICE: Infrared Thermometer (Model:FDIR-V5）

CLASSIFICATION - *ANNEX IX*: *CLASS IIA, RULE 10*

UMDNS/DMDNS: 14036 Thermometers, Infrared

Conformity assessment Route： Annex II (Excluding Section 4) - EC DECLARATION OF CONFORMITY（Full quality assurance）

We, **FAMIDOC Technology Co., Ltd**., herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 March 2010, the amendments by Council Directive 2007/47/EEC.

Standards applied: EN ISO 13485:2016, EN ISO 14971:2012,EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2015, EN60601-1-11:2015,EN ISO 80601-2-56:2017+A1:2020, EN 62304: 2006 +A1:2015,EN 62366-1:2015,EN ISO 10993-1:2010,EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 15223-1-2016; EN 1041:2008+A1:2013, EN ISO 780:2015.

NOTIFIED BODY: SGS Belgium Nv
SGS House Noorderlaan 87 2030 Antwerp Belgium
Tel : +32(0)3 545 48 48
Fax : +32(0)3 545 48 49
Website : www.sgs.com

Identification number: CE 1639

(EC) Certificate(s): CN19/41052

Start of CE-marking: 16 December,2019

EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80,20537 Hamburg,Germany
Dimdi No.:DE/0000040627
Tel: +49-40-2513175, Fax: +49-40-255726
Email: shholding@hotmail.com

Place, Date of Declaration: DONGGUAN,January 29, 2021

Singed on behalf of
FAMIDOC Technology Co., Ltd

Amos Zou
Title: Management Representative

EC Certificate Full Quality Assurance System: Certificate CN19/41052

The management system of

Famidoc Technology Co., Ltd.

No. 212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town,
Dongguan, Guangdong Province, 523853, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 19 May 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 19 May 2011
and first certified by SGS Belgium on 16 December 2019

Certification is based on reports numbered CN/DGG 13545

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Famidoc Technology Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Infrared Thermometer;
Digital Clinical Thermometer;
Electrical Stimulator (TENS/EMS) for relief of pain, Muscle Re-education for treatment of patients with muscular atrophy

Detail model No.:

Infrared Thermometer:
FDIR-V1
FDIR-V2
FDIR-V3
FDIR-V4
FDIR-V5
FDIR-V6
FDIR-V7
FDIR-V8
FDIR-V8-3
FDIR-V9
FDIR-V9-3
FDIR-V10
FDIR-V11
FDIR-V12
FDIR-V13
FDIR-V15
FDIR-V16
FDIR-V17
FDIR-V18
FDIR-V19
FDIR-V20
FDIR-V22
FDIR-V23
FDIR-V24
FDIR-V14(PT3)

Famidoc Technology Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Digital Clinical Thermometer:
FDTH-V0-1
FDTH-V0-2
FDTH-V0-3
FDTH-V0-4
FDTH-V0-5
FDTH-V0-6
FDTH-V0-7
FDTH-V0-8
FDTH-V0-9
FDTH-V0-11
FDTH-V0-12
FDTH-V0-13
FDTH-V0-14
FDTH-V0-15
FDTH-V0-16

Electrical Stimulator (TENS/EMS) for relief of pain, Muscle Re-education for treatment of patients with muscular atrophy:
FDES100
FDES101
FDES102
FDES103
FDES105
FDES106
FDES107
FDES108
FDES113
FDES115
FDES116

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market