MINISTERUL SĂNĂTĂŢII, MUNCII ŞI PROTECŢIEI SOCIALE AL REPUBLICII MOLDOVA
МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА
AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ
MD-2028, mun. Chişinău, str. Gheorghe Asachi, 67-a
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DOCUMENTAŢIE MEDICALĂ / Медицинская документация
FORMULAR / Форма **Nr. 303-2/e**
APROBAT DE MSMPS al RM / Утверждена МЗТСЗ РМ
31.10.11 Nr. 828

Centrul de încercări de laborator acreditat de către Centrul Naţional de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LÎ-044 din 17.02.2018 valabil până la 16.02.2022
Acreditat în Sistemul Ministerului Sănătăţii, Muncii şi Protecţiei Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR

PENTRU PRODUSELE ALIMENTARE ŞI NEALIMENTARE Nr. P-5663/2020

Санитарное заключение для пищевых и непищевых продуктов

din/*от* " 31 " mai a./*г.* 2020

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea şi desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Aparate pentru măsurarea tensiunii arteriale, aparate de aerosolterapie, stetoscoape, termometre m.c. Dr.Frei

sunt conforme Regulamentului (lor) sanitar (e) / *соответствуют санитарному (ым) регламенту (ам)* (se va indica denumirea completă a Regulamentului (lor) sanitar (e) / *указать полное наименование санитарного (ых) регламента (ов)*

Indicaţii Metodice nr.29 FŢ/1683 din 14.05.01, Directiva Europeană 93/42/EEC privind dispozitivele medicale

Organizaţia-producătoare/importatoare, ţara de origine / *организация произв./импортер, страна происхождения*

Italia, EP SPA; China, Shenzhen Pango Electronic Co.,Ltd; Wuxi Medical Instrument Factory; Kangfu Medical Equipment Factory; Honsun (Nantong)Co.,Ltd.

Destinatarul avizului sanitar / *получатель санитарного заключения*

ÎM „DELTA - MEDICA" SRL, Moldova, Chişinău, Durleşti, str.Gribov, 4, ap.32

Ca temei pentru recunoaşterea conformităţii produselor Regulamentului (lor) sanitar (e) menţionat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract nr.FC/DM-2 din 10.12.2019, declaraţii de conformitate, certificate de calitate, aviz sanitar nr.P-1524 din 27.05.2019

(a enumera documentele de însoţire, buletinele de analiză / *перечислить сопроводительные док., протоколы исслед.*)

Caracteristica sanitară a produselor / *санитарная характеристика продукции:*

Parametrii (factorii) / *показатели (факторы)* **Normativul sanitar** / *санитарный норматив*

Aparatele sunt conforme Indicaţiilor Metodice nr.29 FŢ/1683 din 14.05.01, Directivei Europene 93/42/EEC privind dispozitivele medicale

Domeniu de utilizare / *Область применения:* scopuri medicinale

Condiţiile necesare de utilizare, depozitare, transportare, măsurile de securitate / *Необходимые условия использования, хранения, транспортировки, меры безопасности:*

importul, plasarea pe piaţă în condiţiile respectării legislaţiei în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pînă la / *Санитарное Заключение действительно до:* 30 mai 2021

DIRECTORUL AGENŢIEI NAŢIONALE PENTRU SĂNĂTATE PUBLICĂ

Nicolae FURTUNĂ
(numele, prenumele/ Ф.И.О.)

(semnătura / подпись)

L.Ş.

ANSP/HAO3 0001804 03

"DELTA-MEDICA" S.R.L.

Digitally signed by Granaci Boris
Date: 2020.06.17 14:37:04 EEST
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 101165 0003 Rev. 00

Manufacturer:	**Kangfu Medical Equipment Factory** No.380 Ningkang East Road 325600 Yueqing, Zhejiang PEOPLE'S REPUBLIC OF CHINA
EC-Representative:	Luxus Lebenswelt GmbH Kochstr. 1, 47877 Willich, GERMANY
Product Category(ies):	**Digital Thermometers, Infra-red Thermometers, Diagital Blood Pressure Monitors (Sphygmomanometers)**

The Certification Body of TÜV SÜD Product Service GmbH 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 subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH18139701

Valid from: 2019-01-29
Valid until: 2024-01-28

Date, 2019-01-29

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 101165 0003 Rev. 00

Facility(ies):

Kangfu Medical Equipment Factory
No.380 Ningkang East Road, 325600 Yueqing, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q6 101165 0001 Rev. 00

Holder of Certificate: **Kangfu Medical Equipment Factory**
No.380 Ningkang East Road
325600 Yueqing, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Kangfu Medical Equipment Factory
No.380 Ningkang East Road, 325600 Yueqing, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Digital Thermometers / Infra-red Thermometers / Digital Blood Pressure Monitors (Sphygmomanometers)**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH18139701

Valid from: 2019-01-29
Valid until: 2022-01-28

Date, 2019-01-29

I. Preiß
Stefan Preiß

S.R.L. "DELTA-MEDICA" IDNO 1008600039292 INTREPRINDEREA MIXTĂ, REPUBLICA MOLDOVA

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Declaration of Conformity

Manufacture Kangfu Medical Equipment Factory
Address No.380 Ningkang East Road,Yueqing, Zhejiang 325600, PEOPLE`S REPUBLIC OF CHINA

European Representative Lin Sun
Luxus Lebenswelt GmbH
Product Name: Infra-red Thermometers
Model:
KFT-22M corresponds to Dr.Frei MI-100
Product Category IIa
The UMDNS code 14-032

Conformity Assessment Route Directive 93/42/EEC
We declare the compliance of the above medical device with the applicable requirements **rules10** of Appendix IX of Directive 93/42/EEC : All the supporting documents and files are retained under the premises of the manufactures.
Simultaneously meets the requirement of the following Recognized Consensus Standards.

- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC60601-1-11:2015 Medical electrical equipment. Part 1-11:General requirements for basic safety and essential performance. Collateral standard:Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ISO 10993-1:2009 Ophthalmic instruments -- Slit-lamp microscopes
- ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for ir vitro cytotoxricity
- ISO10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO14971:2016 Medical devices-Application of risk management to medical devices
- ISO15223-1:2016 Medical devices--symbols to be used with medical device labels,labelling and information to be suppliedlied--part1:general requirements
- ISO 80601-2-56:2009 medical electrical equipment part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- IEC 62366-2007+A1-2014 Medical devices-Application of usability engineering to medical devices
- MEDDEV2.71 rev4 Clinical evaluation: guidelines for manufacturers and notified institutions under Directive 93/42/EEC and 90/385/EEC

Announcement Organization: TÜV SÜD Product Service GmbH
Address: Ridlerstrasse 6580339 Munich, Germany
Identification Number: CE 0123

Signature:

Date: Jan 23, 2019

Position: Quality Manager

Place: YUEQING