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

Product Service

Certificate

No. Q5 092260 0001 Rev. 01

Holder of Certificate: **Fervid Medical Technology Co., Ltd.**
West 7th floor, Building 2
No.2 ChongQing road
Qiaotou community, Fuyong, Baoan
518103 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Fervid Medical Technology Co., Ltd.
West 7th floor, Building 2, No.2 ChongQing road, Qiaotou community, Fuyong, Baoan, 518103 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design/Development, Production and Distribution of Disposable Inflation Device, Disposable Three-way Stopcock, Disposable Manifolds, Disposable Extension Tube, Disposable Surgical Towel, Disposable Surgical Clamps, Disposable Control Syringes, Disposable Y Connector, Radical Artery Compression Tourniquet, Femoral Compression Device (Manual), Femoral Compression Device (Electric), Disposable Flushing Pipeline and Uroflowmeter**

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, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1922001

Valid from: 2019-10-29
Valid until: 2022-05-12

Digitally signed by Iarovoi Petru
Date: 2021.09.09 14:08:24 EEST
Reason: MoldSign Signature
Location: Moldova

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

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

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in class I in sterile conditions, sterilized systems or procedure packs)

No. G1S 092260 0002 Rev. 00

Manufacturer:

Fervid Medical Technology Co., Ltd.
West 7th floor, Building 2
No.2 ChongQing road
Qiaotou community, Fuyong, Baoan
518103 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Fervid Medical Technology Co., Ltd.
West 7th floor, Building 2, No.2 ChongQing road, Qiaotou community, Fuyong, Baoan, 518103 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Disposable Inflation Device, Disposable Three-way Stopcock, Disposable Surgical Towel, Disposable Control Syringes, Disposable Y Connector, Radical Artery Compression Tourniquet, Femoral Compression Device (Manual), Femoral Compression Device (Electric)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex II. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: GZ1922001

Valid from: 2019-10-25
Valid until: 2021-10-25

Date, 2019-10-25

Stefan Preiß
Head of Certification/Notified Body

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

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DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC

CONCERNING MEDICAL DEVICES

MANUFACTURER: FERVID MEDICAL TECHNOLOGY CO., LTD

ADD:WEST 7 FLOOR, BUILD 2, NO. 2 CHONGQING ROAD, QIAOTOU COMMUNITY, FUYONG, BAOAN, 518053, SHENZHEN, PEOPLE' S REPUBLIC OF CHINA

PRODUCT: RADICAL ARTERY COMPRESSION TOURNIQUET

MODEL : FXZXH-01

CLASSIFICATION : CLASS I*, RULE 1

MD CODE: MD 0102

CONFORMITY ASSESSMENT ROUTE:ANNEX II EXCLUDING 4

WE, FERVID MEDICAL TECHNOLOGY CO., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: SEE HARMONISED STANDARDS LIST

NOTIFIED BODY : TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 M NCHEN, GERMANY

IDENTIFICATION NUMBER: CE 0123

(EC) CERTIFICATE(S): G1S 092260 0002 REV.00

EC REP :Renault-Petersen Limited

EUROPEAN REPRESENTATIVE:5 Bankside, Hanborough Business Park, Witney OX29 8LJ UK

START OF CE-MARKING:2016-08-01

PLACE, DATE OF DECLARATION: *SHENZHEN, 2019/01/18*

SIGNATURE: _____

LI FENG

POSITION: GENERAL MANAGER

FERVID MEDICAL TECHNOLOGY CO.,LTD

HARMONISED STANDARDS LIST

SN	Standard Code	Standard Name
1	MDD93/42/EEC+Amd:2007	Council Directive 93/42/EEC including Amd: 2007
2	ENISO 13485: 2016	Medical devices—Quality management systems- Requirements for regulatory purposes
3	EN ISO14971:2012	Medical devices—Application of risk management to medical devices(ISO 14971:2007, corrected version 2001-10-01)
4	EN ISO 15223-1:2016/Cor.2016	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied Part1: General requirements.
5	MEDDEV 2.7/1 Rev.4: 2016	Guidelines on Medical Devices Clinical Evaluation :A Guide for Manufacturers and Notified Bodies under directive 91/42/EEC and 90/385/EEC
6	ENISO 10993-1 2009	Biological evaluation of medical devices—Part1:Evaluation and testing within a risk management process (ISO10993-1:2009)
7	ENISO 10993-5: 2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
8	EN ISO 10993-7: 2008/AC:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals(ISO 10993-7:2008/Cor 1:2009)
9	EN ISO 10993-10: 2013	Biological evaluation of medical devices-Part10:Tests for irritation and skin sensitization
10	EN ISO 10993-11:2018	Biological evaluation of medical devices-Part11: Tests for systemic toxicity (ISO 10993-11:2006)
11	ASTMF 1980:16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for medical device
12	EN ISO 11135:2014	Sterilisation of health care products — Ethylene oxide — Part 1:Requirements for the development, validation and routine control of a sterilization process for medical devices
13	EN ISO 11737-1:2018	Sterilization of medical devices. Microbiological methods. Tests of sterility performed in the definition, validation and maintenance of a sterilization process

14	EN ISO 11737-2:2009	Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products
15	EN ISO 11607-1:2017	Packaging for terminally sterilized medical devices—Part1:Requirements for materials, sterile barrier systems and packaging systems
16	EN ISO 11607-2:2017	Packaging for terminally sterilized medical devices-Part 2: Validation requirements for forming, sealing and assembly process
17	EN ISO 14644-1：2015	Cleanrooms And Associated Controlled Environments - Part 1: Classification of air cleanliness by particle concentration
18	EN ISO 14644-2：2015	Cleanrooms And Associated Controlled Environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
19	EN 556-1:2001/AC: 2006	Sterilization of medical devices-Requirements for medical devices to be designated "Sterile"--Part 1:Requirements for terminally sterilized medical devices
20	ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements
21	ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization process
22	MEDDEV 2.12-1 REV.8 :2013	Guidelines on a medical devices vigilance system
23	MEDDEV 2.12-2 REV.2: 2012	Guidelines on a medical devices: Post market clinical follow-up studies- A guide for manufacturers and notified body.