

Keewell Medical Technology Co., Ltd

Declaration of Conformity

Manufacturer: **Keewell Medical Technology Co., Ltd.**

Xiananyi Industrial Zone, Pingzhou, Nanhai Foshan, Guangdong
528251, P.R.China

European Representative: Wellita International BV

Franciscuslaan 22, 9112 Sinaai-Waas, Belgium

Product: Blood and Infusion Warmer

Model: QW618, FT800, FT1800, FT2800, FT70

Classification: (According to the Annex IX of MDD93/42/EEC Rule 9)IIb

Conformity assessment Route: Annex II of MDD93/42/EEC

The Keewell declares in sole responsibility that the above-mentioned product meets the provisions of the Council Directive 93/42/EEC for medical devices as transposed into national law. All supporting documentation is retained under the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the related Annex II certificate issued by the notified body.

Standards applied: list of (harmonized) standards for which documented evidence of compliance can be provided as *attachment A*

Notified Body: **MEDCERT GmbH**

Notified Body Address: **Pilatuspool 2, 20355 Hamburg**

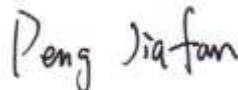
Notified Body Code: **0482**

Certificate No.: **7408GB410200127**

Expiry Date: **2024-05-27**

Place, Date of Issue: *Foshan, China 2021. 08. 05*

Signature:



General Manager

Keewell Medical Technology Co., Ltd

Attachment A

Applied standards:

EN ISO 13485:2016

Medical devices - Quality management systems - Requirements for regulatory purposes

EN ISO 14971:2012

Medical devices - Application of risk management to medical devices

EN ISO 15223-1:2016

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN 1041:2008

Information supplied by the manufacturer of medical devices

EN60601-1:2006

Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

EN 60601-1-8:2007+A11:2017

Specifies basic safety and essential performance requirements and tests for alarm systems in medical electrical equipment and medical electrical systems and to provide guidance for their application.

EN 60601-1-2:2015

Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

EN 62366-1:2015

Medical devices - Application of usability engineering to medical devices

EN 62304:2006/AC:2008

Medical device software - Software life-cycle processes

EN ISO 14155:2011

Clinical investigation of medical devices for human subjects -good clinical practice

ASTM F 2172-02 (2011)

Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers

MEDDEV Guides