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: Peng Jiafan General Manager

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