MEDIHUB Co., Ltd.

#108, 201 SA Tower, 175-LS-ro, Gunpo-si, Gyeonggi-do, 15808 Korea

EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of MEDIHUB Co., Ltd. We herewith declare that the under-mentioned products are in conformity with the General Safety and Performance Requirements and the Regulation (EU) 2017/745 on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Product Name: Digital Warmer
Model Name[Model name]: i-Ject ON

Basic UDI-DI:
SRN: KR-MF-000011971

Classification: Class IIX (Regulation (EU) 2017/745 on medical devices Annex VIII Rule 13)
Conformity Assessment Route: Annex IX, Regulation (EU) 2017/745 on medical devices

Applied Standard: EN ISO 13485:2016/AC:2016+AC:2018, EN ISO14971:2019, EN ISO 15223-1:2021, ISO 20417:2021, IEC 61010-1:2010, IEC 61010-2-040:2020, EN 60601-1-2:2015, EN 62366-1:2015, MEDDEV 2.7/1 [Rev.4]:2016, MEDDEV 2.12/1 [Rev.8]:2013, MEDDEV 2.12/2 [Rev.2]:2012, EN62304:2006, /AC:2008

Manufacture: MEDIHUB. Co., Ltd.
EC Representative: KTR Europe GmbH
Mergenthalerallee , 77 65760 Eschborn
Email: ktreurope@ktreurope.de
SRN: DE-AR-000005685

GMDN Code : 15610 (Warmer)
EMDN Code : W0207900 (Thermostatic water bath)
EC Certificate:MH05-I-JECT-001

CE

Signature:

Hyeoncheol Yeom / CEO

Place of Issue: Gyeonggi-do, Korea
Date of Issue: Start of CE Marking