Declaration of Conformity

to Council Directive 93/42/EEC concerning Medical Devices

Sino Medical-Device Technology Co., Ltd.
6th Floor, Building 15, No.1008, Songbai Road, Nanshan District, 518055 Shenzhen, P.R.C

Medical Device Name: Syringe Pump
Model: SN-50C6, SN-50C66, SN-50C6T, SN-50C66T, SN-50C66R, SN-50C66TR, SN-50C66TS, SN-50C66TSR
SN-50F6, SN-50F66, SN-50F66R, SN-50T66, SN-50T66R

Classification - Annex IX: Class IIb, Rule 11
Conformity Assessment Route: Annex II excluding (4)

We, the manufacturer, 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 and the manufacturer is exclusively responsible for the Declaration of Conformity.

Standards applied: *see attached list of standards for which documented evidence of compliance can be provided.*

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Germany

identification number 0123

(EC) Certificate(s): G1 081494 0016

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Start of CE-marking: 2012-10-16

Place, Date of Declaration: Shenzhen, 2019-01-04

Signature:

Name: Chen Aidi
Position: Management Representative

Digitally signed by Cucu Vasile
Date: 2020.06.24 17:11:34 EEST
Reason: MoldSign Signature
Location: Moldova

List of harmonized standards

No.	Harmonized Standard	Application
1	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
2	EN 1041:2008	Information supplied by the manufacturer with medical devices
3	EN 60601-1:2006/A1:2013	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
4	EN 60601-1-2:2015	Medical electrical equipment - General requirements for safety - Collateral standard: Electromagnetic compatibility; Requirements and tests
5	EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
6	EN 60601-1-8:2007/A11:2017	Medical electrical equipment Part 1-8: General requirements for safety Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems First Edition
7	EN 62304:2006/AC:2008	Medical device software – Software life cycle processes
8	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
9	IEC60601-2-24:2012	Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers
10	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices