

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: Infusion Pump

Model: SN-1600VR, SN-1600V, SN-1800VR, SN-1800V, SN-2000VR,
SN-2000V

Classification - Annex IX: Class IIb, Rule 11

Conformity Assessment Route: Annex II.3

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 17 08 81494 013

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, Date: 2018-03-23

Signature:

Name: Chen Aidi

Position: Management Representative

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 60601-1-2:2007/AC:2010	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/AC:2010	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	ISO 14971:2007	Medical devices - Application of risk management to medical devices