

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES**



Manufacturer:

MEDCAPTAIN MEDICAL TECHNOLOGY CO., LTD.
12th Floor, Baiwang Research Building, No.5158 Shahe West Road,
Xili, Nanshan, 518055 Shenzhen, Guangdong, PEOPLE'S
REPUBLIC OF CHINA

Medical Device:

Infusion Pump:
SYS-6010, SYS-6010T, SYS-6010A, SYS-70, MP-60, MP-60A,
MP-60T, MP-60C, HP-60, HP-60 PRO, HP-60C, HP-60C PRO

Syringe Pump:
SYS-3011, SYS-3010, SYS-50, SYS-52, MP-30, MP-30A,
MP-30T, HP-30, HP-30 PRO, HP TCI, HP TCI PRO, HP-30 Neo

Classification - Annex IX:

Class IIb, Rule 11,

Conformity assessment Route:

Annex II Excluding 4

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices; including, on March 21, 2010, the amendments by Council Directive 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer. The manufacturer is exclusively responsible for the DoC.

Notified Body:

TÜV SÜD Product service GmbH
Ridlerstraße 65, D-80339 München, Germany

Identification number

0123

(EC) Certificate(s):

NO.G1 086916 0023 Rev.00



European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Start of CE-Marking:

2017-04

Place, Date of Issue:

Shenzhen, 2019-08-26

Signature:



Name of Authorized Signatory:

Miss Sun Yafei

Position Held in Company:

Management Representative