DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: HEDY Medical Device Co.,Ltd.
No.286,Science Avenue, Guangzhou High and New Tech Development Zone
Guangzhou,510663,P.R.China

MEDICAL DEVICE: Infusion pump （i7,ip-3）

CLASSIFICATION - *ANNEX IX:* Class IIb, Rule11

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 OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 M NCHEN, GERMANY

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G1 15 10 93293 002

EC REP
EUROPEAN REPRESENTATIVE: Renault-Petersen Limited
5 Bankside,
Hanborough Business Park
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UNITED KINGDOM

START OF CE-MARKING: JANUARY 20, 2016

PLACE, DATE OF DECLARATION: GuagnZhou,January 20, 2016

SIGNATURE:

NAME:
POSITION: CEO