DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC 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: Syringe Pump (s7, sp-3, TCI-7)

CLASSIFICATION - *ANNEX IX*: Class IIb, Rule11

CONFORMITY ASSESSMENT ROUTE: *ANNEX II.4*

WE, HEDY MEDICAL DEVICE CO.,LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC 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.

STANDARDS APPLIED: *SEE ATTACHED LIST OF ANNEX 1*

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, 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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OX29 8LJ UK
UNITED KINGDOM

START OF CE-MARKING: January 20, 2016

PLACE, DATE OF DECLARATION: GuagnZhou,November 1, 2017

SIGNATURE:

NAME:

POSITION: Management representative