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

MANUFACTURER: CHANGSHA DEEPMED MEDICAL TECHNOLOGY CO,.LTD
ADDRESS:ROOM307-310,NO.2 PLANT,NO.586,DONGFANGHONG ROAD,HI-TECH ZONE,CHANGSHA 410205,CHINA

MEDICAL DEVICE: SYRINGE PUMP, MODEL:DPFUSION SP1,DPFUSION SP3,RIDICON P-1800,RIDICON P-1800D

CLASSIFICATION - ANNEX IX: CLASS IIB, RULE11

CONFORMITY ASSESSMENT ROUTE: ANNEX II EXCLUDING (4)

WE, THE MANUFACTURER, EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY, AND 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: 0123

(EC) CERTIFICATE(S): G1 101172 0003 Rev.00

EC REP
EUROPEAN REPRESENTATIVE: LUXUS LEBENSWELT GMBH
ADDRESS:KOCHSTR.1,47877,WILLICH,GERMANY

START OF CE-MARKING: 2019-11-28

PLACE, DATE OF DECLARATION: CHANGSHA 410205,CHINA, 2019.12.01

SIGNATURE:

NAME: HUANG LAN
POSITION: GM