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

MANUFACTURER: CHANGSHA DEEPMED MEDICAL TECHNOLOGY CO..LTD

ADDRESS:ROOM 709 - 717, BUILDING 1, HAIPING PARK, No. 229, GUYUAN ROAD, HI-TECH

ZONE, 410205 CHANGSHA, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: SYRINGE PUMP, MODEL: DPFUSION SP1, DPFUSION SP3,

DPFUSION SPD2, 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 MUNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1 1011720003 Rev. 01

EC REP

SIGNATURE:

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, 2020.09.15

NAME: HUANGLAN

POSITION: GM