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

MANUFACTURER: MEDA Co., LTD

ADDRESS: F2C, F3D, F4C, F5, F6C, Building C2, Xinmao Science Skill Park, Huayuan Industry Development Area, 300384 Tianjin, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: BLADDER SCANNER
TYPE: MD-6000P *UMDNS CODES: 15659*

CLASSIFICATION - *ANNEX IX*: *CLASS **IIA**, RULE 10*

CONFORMITY ASSESSMENT ROUTE: *ANNEX **II.3***

WE, MEDA Co., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS FULLY RESPONSIBLE FOR THE MEDICAL DEVICE PRODUCED.

STANDARDS APPLIED:

EN ISO 13485: 2016; IEC 60601-1:2005/AMD1:2012; IEC 60601-1-2:2014; IEC 60601-2-37:2007/AMD1:2015; IEC62304:2015; EN ISO 14971:2012; EN ISO15223-1:2016; EN 1041: 2008; ISO 10993-1:2018; IEC62366-1:2015 and IEC 60601-1-6:2010/AMD1:2013

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

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): G1 053996 0012 REV. 02

EC REP

EC-REPRESENTATIVE: ***Shanghai International Holding Corp. GmbH (Europe)***
Eiffestrasse, 80, 20537, Hamburg, Germany
Tel: 0086-021-65951371，0049-40-2513175，Fax: 0049-40-25572

START OF CE-MARKING: 2019-05-29
PLACE, DATE OF DECLARATION: *TIANJIN, CHINA 2020-12-23*

SIGNATURE:

NAME: JI JIANJUN
POSITION: GENERAL MANAGER