EC Declaration of Conformity Page Page 1 of 1 Product Name: Ultrasound Bladder Volume Scanner Version/Rev. A/2

Declaration of Conformity

MDT-QT/EC-17005

Ver. B

Manufacture

Address

Chengdu Mediate Technology Co., Ltd.

No.237,2F, Section1, No.1388 Middle Section Tianfu

Ave., High-tech Zone, Chengdu, (Sichuan) Free Trade

Test Zone, P. R. China 610064

European

JCP Holding B V

Representative

Vinkenissestraat 10, 4411CD Rilland-Bath, The

Netherlands

Product Category

Ultrasound Bladder Volume Scanner

BVS-Lite, BVS-Pro, BVS-Pro W

Models Classification

Ila based on MDD 93/42/EEC annex IX rule 10

The UMDNS code

16241

Conformity Assessment Route

Annex II without Chapter 4

We declare the compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. The manufacturer is exclusively responsible for the DOC. All the supporting documents and files are retained under the premises of the manufactures.

Notified Body: TÜV SÜD Product Service GmbH, Ridlestrasse. 65,80339

München, Germany.

Notified body identification number: 0123 Certificate: G1 092389 0007 Rev.00 Expire date of the Certificate: 2024-5-26

Start of CE-Marking:

BVS-Lite

September, 2016

BVS-Pro

September, 2016

BVS-Pro W

September, 2018

Place, Date of Issue: Chengdu China, March 16, 2020

Signature:

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_2020.03.17

Name: Lulu Yuan

Position: Management Representative