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

MANUFACTURER: Qingdao DMD Medical Technology Co., LTD

No.873 Heyuan Road, Hetao street, Hongdao Economic Zone, Qingdao,

266113, China

MEDICAL DEVICE: LIGATING CLIPS(TI)

TCLT100,TCLT200,TCLT300;TCLT400;TCLT100-24;TCLT200-24;TCTL5200; TCTL1201;TCTL1202;TCTL2200;TCTL3200;TCTL4200;TCTL1201-24;TCTL2200-24

CLASSIFICATION - ANNEX IX: CLASS IIB, RULE 8

CONFORMITY ASSESSMENT ROUTE: ANNEX II.3

We, <u>THE MANUFACTURER</u>, 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. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

(EC) CERTIFICATE(S): EC CERTIFICATE(S) NUMBER(S)

No.G1 090932 0010 Rev.02

EC REP

EUROPEAN REPRESENTATIVE: MedNet EC-REP GmbH

Borkstrasse 10 48163 Muenster GERMANY

START OF CE-MARKING: 2016.06.07

PLACE, DATE OF DECLARATION: Qingdao 2020.02.29

SIGNATURE:

NAME: YAN NIU

POSITION: MANAGEMENT REPRESENTATIVE

Ref: EN ISO/IEC 17050-1 revision date: June 2017