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

MANUFACTURER:	DENJOY DENTAL CO., LTD F4, A4 BUILDING, LUGU MEDICAL DEVICE PARK, NO.229 GUYUAN ROAD, CHANGSHA, 410205 P.R.CHINA
MEDICAL DEVICE:	PULP TESTER *(MD1106) GMDN [13187]* Model：DY310
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX V.3 + VII*

WE, DENJOY DENTAL CO., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 13485:2016 , EN ISO 14971:2012, EN ISO 15223-1:2012, EN 1041:2008, EN 60601-1:2006, EN 60601-1-2:2007, EN ISO 10993-1：2009, EN ISO 10993-5：2009, EN ISO 10993-10：2010, EN 62304:2006, EN 62366:2008.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	Q60765130007
EC REP EUROPEAN REPRESENTATIVE:	*LANDLINK GMBH* *DORFSTRASSE 2/4, 79312 EMMENDINGEN, GERMANY*

START OF CE-MARKING: *2014-12-03*

PLACE, DATE OF DECLARATION: *CHANGSHA, 2019-12-13*

SIGNATURE: _____

NAME: CHEN QINGLIANG

POSITION: PRESIDENT