Alicn Medical (Shenzhen) Co., Ltd.

Declaration of Conformity

MANUFACTURER: Alicn Medical(Shenzhen) Co., Ltd.
3/F,No4 Building,Niucheng industrial Park,XiLi,Nanshan District,
518055 Shenzhen,GuangDong Province,China

MEDICAL DEVICE: NEUROMUSCULAR STIMULATOR, *POCKET TENVIT*

CLASSIFICATION - *ANNEX IX*: *CLASS IIB, RULE 9*

CONFORMITY ASSESSMENT ROUTE: *ANNEX V+ ANNEX VII*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: *(HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

（1）EN 60601-1:2007； *（2）EN 60601-1-2:2010；* *（3）IEC62304:2006;*
（4）ISO 10993-1:2009； *（5）ISO 10993-5:2009；* *（6） ISO 10993-10:2010；*
（7）IEC60601-1-6:2011； *（8）IEC 60601-2-10: 2010；* *（9）IEC 60601-1-11:2010;*

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

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S):

EC REP

EUROPEAN REPRESENTATIVE: Renault-Petersen Limited
Couching House, Couching Street, Watlington, Oxfordshire OX495PX UK.

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: *SHENZHEN, 2015-03-04*
SIGNATURE:
NAME: MEISONG FANG
POSITION: (GM)