

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:

ULTRASOUND THERAPY DEVICE, *BIOSONYC PRO*

CLASSIFICATION - ANNEX IX:

CLASS IIA, 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.

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|------------------------|-------------------------|------------------------|
| (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 60601-2-5:2001; | |

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):



EUROPEAN REPRESENTATIVE:

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

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: SHENZHEN, 2013-03-12

SIGNATURE:

NAME: MEISONG FANG POSITION: (GM)

