

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:

CRYOTHERAPY DEVICE, CRYOS CARD

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; |                        |                        |

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, 2015-01-29

SIGNATURE:

NAME: MEISONG FANG

POSITION: (GM)

