

Declaration of Conformity

File NO	AET-R1X-CE-05	Version	V1.2	Date	2019-10-18
---------	---------------	---------	------	------	------------



MANUFACTURER:

Alicn Medical Shenzhen, Inc
4/F, B Building, Shenfubao Modern Optical Factory, Kengzi
Street, Pingshan District, 518122 Shenzhen City, PEOPLE'S
REPUBLIC OF CHINA

MEDICAL DEVICE: Clinical Infrared Thermometer
Model: AET-R1B1, AET-R1B6, AET-R161

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX V

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC
OF CONCERNING MEDICAL DEVICES;
WE ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC.
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 ISO 80601-2-56:2009;
- (2) EN 60601-1:2006+A1:2013;
- (3) IEC 60601-1-2:2007;
- (4) ISO 10993-1:2009;
- (5) ISO 10993-5:2009;
- (6) ISO 10993-10:2010;
- (7) IEC62304:2015;
- (8) IEC60601-1-11:2015;

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

0123

(EC) CERTIFICATE(S):

G2 078453 0014 REV.01

EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING: 2012-02-08

PLACE, DATE OF DECLARATION: SHENZHEN, 2019-10-18

SIGNATURE: _____

NAME: MEISONG FANG

POSITION: (GM)