

Alicn Medical Shenzhen, Inc.

Declaration of Conformity

File NO	AET-R1X-CE-06	Version	V1.2	Date	2019-10-18
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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

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 60601-1-2:2014;
(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)