Alicn Medical Shenzhen, Inc.

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*

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 M NCHEN, 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)

Digitally signed by Grabazei Alexandru
Date: 2020.06.18 14:25:11 EEST
Reason: MoldSign Signature
Location: Moldova