

EU Declaration of Conformity


File No.	AET-R1X-CE-05	Version	V1.1	Date	2022-06-11
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EU Declaration of Conformity**TO REGULATION (EU) 2017/745 OF THE EUROPEAN****PARLIAMENT AND OF THE COUNCIL**

Manufacturer:	Name: Alicn Medical Shenzhen, Inc Address: Room 410, Building A, 3rd Sub-park, Leibo Zhongcheng Life Science Park, No.22 Jinxiu East Road, Jinsha Community, Kengzi Street, Pingshan District, 518118 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000001920
Authorised Representative:	Name: CMC Medical Devices & Drugs S.L. Address: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain SRN: ES-AR-000000293
Product Name:	Infrared Thermometer
Trade Name:	Infrared Thermometer
Model:	AET-R1B1
CND Code:	V030101 THERMOMETERS
GMDN Code:	17888 Thermometer, infrared, skin
Basic UDI-DI:	69537756R1B1VP
Intended Use/Intended Purpose:	The Infrared Thermometer is intended for measuring human body temperature of people aged 3 months and above by detecting infrared heat from non-contact(about 1.5-5.0cm distances) with the forehead in the home or hospital environment.
Risk Class:	Class II a
Classification Rule:	Rule 10 in Chapter III of Annex VIII of the Regulation (EU) 2017/745
Conformity Assessment Route	Chapter I and III of Annex IX of the Regulation (EU) 2017/745
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.	
Applied Standards:	ISO 80601-2-56:2017+A1:2018; IEC 60601-1:2005+A1:2012; IEC 60601-1-2:2014; IEC 60601-1-11:2015;

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	IEC 60601-1-6:2010+A1:2013; IEC 62366-1:2015; IEC 62304:2015; ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2010;		
Notified Body:	TÜV SÜD Product Service GmbH Address: Ridlerstraße 65, 80339 MÜNCHEN, Germany Phone : +49 (89) 50084261 Fax : +49 (89) 50084230		
Identification Number:	0123		
(EC) Certificate(s):	G10 078453 0016 Rev.00	Valid until	2027-06-06
Start of CE-marking:	2022-06-07		
Place, Date of Issue:	Shenzhen, Guangdong 2022-06-11		
Signature:	 <hr style="width: 20%; margin: 0 auto;"/> Name: Meisong Fang Function: General Manager		