

EU Declaration of Conformity

File No.	AET-F3X-CE-05	Version	V1.1	Date	2024-09-18
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EU Declaration of Conformity**TO REGULATION (EU) 2017/745 OF THE EUROPEAN****PARLIAMENT AND OF THE COUNCIL**

Manufacturer:	Alicn Medical Shenzhen, Inc Room 4C, Building 1, Zhongcheng Biomedical Industrial Park, No. 21 Linhui Road, Jinsha Community, Kengzi Street, Pingshan District, 518118 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA
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:	Electronic Thermometer
Trade Name:	Electronic Thermometer
Model:	AET-F344,AET-F345,AET-F346
CND Code:	V030101
Basic UDI-DI:	69537756F3XXXT
SRN:	CN-MF-000001920
Intended Use:	The Electronic Thermometer is intended to measure the human body temperature in regular mode axillary, and the devices are non-sterile, reusable for clinical or home use on people of all ages.
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+A2:2020; IEC 60601-1-2:2014+A1:2020; IEC 60601-1-11:2015+A1:2020; IEC 60601-1-6:2010+A2:2020; IEC 62366-1:2015+A1:2020;

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	IEC 62304:2015; ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2021; ISO 10993-23:2021;		
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.01	Valid until	2027-06-06
Start of CE-marking:	2022-06-07		
Place, Date of Issue:	Shenzhen, Guangdong 2024-09-18		
Signature:	 Name: Meisong Fang Function: General Manager		