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Intended measurement site	Forehead	
Measurement range	32°C~42.9°C	
	89.6°F~109.2°F	
Laboratory measurement	±0.2°C (35.0°C~42.0°C)	
precision	±0.3°C (others)	
Display Precision	0.1°C/°F	
Measurement units	°C/°F	
Operation condition	10°C~40°C, RH≤93%	
**	(non-condense),	
	70kPa ~106kPa	
Storage and transport	-20°C~55°C, RH≤93%	
condition	(non-condense),	
	50kPa ~106kPa	
Dimensions	140x40x40(mm)	
Weight	About 95g	
1 30%	(include battery)	
Expected service life	6 years	





Fever Alarm Function

- When body temperature range from 37.5°C~38.4°C, the thermometer will emit a Orange backlight and 3 short beep to remind you
- When body temperature temperature range from 38.5°C~42.9°C, the thermometer will emit a Red backlight and 5 short beep to remind you.

















32 SET OF DATA STORAGE

Store up to 32 sets of readings are recorded for better tracking the changes of body temperature, support clinical febrile diagnosis.







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Attestation of Conformity

No. ICR Polska/M3600006



Name and address of Registered Manufacturer: Jiangxi Dayou Medical Technology Co., Ltd. Stanard Plants Building B7, Yangguang Road, Wanzai Industrial Zone, Wanzai County, Yichun city, Jiangxi Province,

Infrared Thermometer Product name:

DY-A200, DY-A201, DY-A202, DY-A203, DY-A600, DY-A601, DY-A602, NX-2000 Product type/model:

Trade mark:

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC

EC Declaration of Conformity (Annex VII of Directive Conformity assessment

procedure: 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

EN 60601-1:2006+A1:2013, EN 60601-1-2:2015 Applied normative documents:

Applied Quality

Management System

This AoC will remain valid only if Quality Management System Certificate remains valid. The assessment process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test report made by:

Shanghai GOM Testing & Technical Co., Ltd.

No. of test report: GOM200320282T Issue date: 19.03.2020 **Expiration date:** 18.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-3125.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standard.



Director: Rafał Kalinowski

Warsaw, 19. 03. 2020.

ICR Polska Co. Ltd.

ul. Plac Przymierza 6, 03-944 Warszawa www.icrpolska.com, e-mail: icrpolska@icrqa.com





Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

Jiangxi Dayou Medical Technology Co., Ltd.
Stanard Plants Building B7, Yangguang Road, Wanzai Industrial Zone, Wanzai County, Yichun city, Jiangxi Province, China

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through Shenzhen Lintek certification Group Co.,Ltd.

Owner/Operator Number:: 10067829

Listing No.	Proprietary Name:	Device Class:	Device Name:
D387012	Infrared Thermometer DY-A200, DY-A201, DY- A202, DY-A203, DY-A600, DY-A601, DY-A602, NX-2000	1	Thermometer, clincal color change

Remark

Assumes no liability to any person or entity in connection with the foregoing. Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."



Certificate Of Conformity



No.: BGAC20049104R

Applicant...... Jiangxi Dayou Medical Technology Co., Ltd.

Address..... Stanard Plants Building B7, Yangguang Road, Wanzai Industrial

Zone, Wanzai County, Yichun city, Jiangxi Province, China

Manufacturer...... Jiangxi Dayou Medical Technology Co., Ltd.

Address..... Stanard Plants Building B7, Yangguang Road, Wanzai Industrial

Zone, Wanzai County, Yichun city, Jiangxi Province, China

Trademark..... N/A

Product..... Infrared thermometer

Model(s) DY-A200, DY-A201, DY-A202, DY-A203, DY-A600, DY-A601,

DY-A602, NX-2000

Directives Directive 2011/65/EU and Amendment Directive (EU) 2015/863

Standards..... IEC 62321-3-1:2013, IEC 62321-5:2013, IEC 62321-4:2017,

IEC 62321-7-1:2015, IEC 62321-7-2:2017, IEC 62321-6:2015,

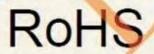
EN 14372:2004

Report No. BG2004TR9104R

Remark:

The certificate of conformity is based on an evaluation of sample if the above mentioned Product.

The EUT described above has been examined by us with the listed standards and found in compliance with the Directive 2011/65/EU and Amendment Directive (EU) 2015/863. It is possible to use RoHS marking to demonstrate the compliance with this RoHS Directive.



Approved by/Date:

Apr.08, 2020

Shenzhen Bory Technology Service Co., Ltd.

Tel: +86 755 2328 6925 Fax: +86 755 2328 6935 Email: Service@bory.biz http: www.bory.biz 501, Building 10, Xinlitang Building, Gangbei Industrial Park, Huanglian Community, Hangcheng Street, Baoan District, Shenzhen, Guangdong, China







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