

MODELO: JXB-182
PAIS DE ORIGEN: CHINA
FABRICANTE: GUANGZHOU BERRCOM MEDICAL DEVICE CO. LTD



DESCRIPCIÓN DEL PRODUCTO

La toma de temperatura nunca ha sido tan fácil con el termómetro sin contacto. El Berrcom proporciona comodidad, precisión al tomar una temperatura con solo presionar un botón, Berrcom toma la temperatura de una persona de manera instantánea y precisa sin la necesidad de ningún contacto físico, simplemente apunte el Berrcom a la frente del paciente, haga clic en "Escanear" y se mostrará su temperatura al instante. Berrcom también viene equipado con tres modos diferentes de toma de temperatura: temperatura corporal, ambiente y superficie.

Especificaciones del producto	Medidas
Tamaño de la unidad: 187 * 120 * 57 mm (LxWxH) Peso de la unidad (sin batería): 80 g Resolución de pantalla de temperatura: 0.1C (0.1F) Consumo: ≤300mW Memoria: 32 juegos Condición de uso normal: Temperatura ambiente: 10 ° C ~ 40 ° C (50 ° F ~ 104 ° F) Humedad relativa: ≤85% Alarma audible si la temperatura es superior a 38 ° C (100.4 ° F) Se puede mostrar en grados Celsius o Fahrenheit La longevidad usa 100,000 lecturas Elimina la contaminación cruzada. Higiénico y fácil de usar Precisión: ± 0.3 ° C (0.6 ° F) Tiempo de respuesta: 1 seg. Edad sugerida: recién nacido y hasta Apagado automático: <30 segundos	Distancia de medición: 3cm ~ 5cm (1.2in ~ 2in) Rango de medición: Modo cuerpo: 32 ° C ~ 42.9 ° C (89.6 ° F ~ 109.2 ° F) Modo de temperatura superficial: 0 ° C ~ 60 ° C (32 ° F ~ 140 ° F) Modo de habitación: 0 ° C ~ 40 ° C (32 ° F ~ 104 ° F) Precisión: 32.0 ° C ~ 34.9 ° C (89.6 ° F ~ 94.8 ° F) ± 0.3 ° C (± 0.6 ° F) 35.0 ° C ~ 42.0 ° C (95 ° F ~ 107.6 ° F) ± 0.2 ° C (± 0.4 ° F) 42.1 ° C ~ 42.9 ° C (107.8 ° F ~ 109.2 ° F) ± 0.3 ° C (± 0.6 ° F)



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 082883 0014 Rev. 00

Manufacturer:

**Guangzhou Berrcom
Medical Device Co., Ltd**
No.38 Huanzhen xi Road
Dagang Town, Nansha
511470 Guangzhou, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Guangzhou Berrcom Medical Device Co., Ltd
No.38 Huanzhen xi Road, Dagang Town, Nansha, 511470
Guangzhou, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Non-contact Infrared Thermometer, Digital Thermometer, Ear Thermometer, Nasal Aspirator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

GZ19049CN01

Valid from:

2019-05-15

Valid until:

2023-07-28

Date,

2019-05-15

Stefan Preiß

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**



MANUFACTURER: Guangzhou Berrcom Medical Device Co., Ltd.
NO.38 Huanzhen Xi Road, Dagang Town Nansha 511470 Guangzhou, Guangdong
PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Non-contact Infrared Thermometer
JXB-182, JXB-178, JXB-179, JXB-180, JXB-181, JXB-183, JXB-185, JXB-186, JXB-188, JXB-189, JXB-190, JXB-191, JXB-192, JA001, JXB-301, JXB-302, LMP001, JXB-195, JXB-303, JXB-307, JXB-308, JXB-182B, JXB-311

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX II.3

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. (NOTE: IT IS SUGGESTED THAT THIS LIST STATE THE STANDARDS' FULL NAME AND DATE OF ISSUE AND INCLUDES ALL AMENDMENTS. A CROSS REFERENCE TO THIS STANDARDS LIST FROM THE ESSENTIAL REQUIREMENTS CHECKLIST MINIMISES DOCUMENT CHANGES IN THE EVENT OF STANDARDS RE-ISSUE OR AMENDMENT).

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

EC CERTIFICATE(S) NUMBER(S) NO. G1 082883 0014 REV.00
SHOW ONLY THE EC CERTS WITH A SCOPE THAT COVERS THE PRODUCTS LISTED



EUROPEAN REPRESENTATIVE:

Wellkang Ltd; Addr: The Black Church, St. Mary's
Place, Dublin 7, D07 P4AX, Ireland;
Tel: +353(1)4433560
E-mail: AuthRep@CE-marking.eu

(THERE MAY BE ONLY ONE EC REP FOR EACH PRODUCT TYPE FOR ALL THE EU)

START OF CE-MARKING:

2012-09-07

PLACE, DATE OF DECLARATION:

GUANGZHOU 511470, 2019-05-15

SIGNATURE



NAME: KEN GUO

POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)



Certification of FDA Registration Service

This document provides notification of the registration number assigned to the client's establishment.

Establishment: Guangzhou Berrcom Medical Device Co., Ltd
Address: No.38 Huanzhen xi Road, Dagang Town, Nansha
Guangzhou, Guangdong, CHINA 511470

Owner/Operator No.: 10032524
Registration No.: 3008395508

Listing No.	Premarket Submission No.	Product Codes	Device Name	Activities
D362541	K191570	FLL	Thermometer, electronic, clinical	Foreign Exporter Manufacturer
D208752	K130232	DXN	SYSTEM, MEASUREMENT,	Foreign Exporter Manufacturer
D208750	K130231	FLL	Thermometer, electronic, clinical	Foreign Exporter Manufacturer
D217608	Exempt	KMA	IRRIGATOR, POWERED NASAL	Foreign Exporter Manufacturer
D309292	K163603	FLL	Thermometer, electronic, clinical	Foreign Exporter Manufacturer

Mr. Field Fu
SHENZHEN JOYANTECH CONSULTING CO., LTD
www.cfdac.com

Certification No.: FDA 201011-013

Validity: Dec 20, 2019 -D Dec 31, 2020



CCIC (SHENZHEN) ENVIRONMENTAL SERVICE CO.,LTD.

Test Verification of Conformity

Certificate No.: CTC18071108R2

R/C: 75215

Issued Date: Jan 23, 2019

The sample, as described herewith, was tested pursuant to the testing standard :

IEC 62321-3-1-2013, IEC 62321-5-2013, IEC 62321-6-2015, IEC 62321-7-1-2015

and all the test results comply with the requirements of :

RoHS Directive 2011/65/EU

Restriction of the use of certain Hazardous Substance
in electrical and electronic equipment

Applicant: Guangzhou Berrcom Medical Device Co., Ltd.

No.38 Huanzhen Xi Road, Dagang Town, Nansha, Guangzhou, China

Manufacturer: Guangzhou Berrcom Medical Device Co., Ltd.

No.38 Huanzhen Xi Road, Dagang Town, Nansha, Guangzhou, China

Sample Name: Non-contact Infrared Thermometer

Sample Model(s): JXB-182, JXB-178, JXB-180, JXB-183, JXB-186, JXB-188, JXB-189, JXB-190, JXB-191, JXB-192, JXB-195, JXB-301, JXB-302, JA001, LMP001, JXB-308, JXB-182B, JXB-178B, JXB-183U

Laboratory: CCIC (Shenzhen) Environmental Service Co., Ltd.

Floor 2, Minlida Industrial Park, Honghualing Industrial Zone, Nanshan District, Shenzhen, Guangdong, China

Tel: 86-755-86632632 Fax: 86-755-86632632

Http: // www.ccicshenzhen.com.cn E-mail: zjjc@sz.ccic.com



Note:

The certification is only valid for the submitted sample(s), in conjunction with the test data detailed in our test report

No. : ZJC18071108R2

For and on behalf of
CCIC (Shenzhen) Environmental Service Co., Ltd.

Authorized by:

Renyou. Yang

