

A3 Berrcom Thermometer



TUV SUD
ZERTIFIKAT ◆ CERTIFICATE ◆ 證書 ◆ CERTIFICADO ◆ CERTIFICAT



Benannt durch/Designated by
Zertifizierten der Länder
für Gesundheitsschutz
von Arzneimitteln und
Medizinprodukten
ZLG-85-244.10.08



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



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.cfdpa.com

Certification No.: FDA 201011-013

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