

**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)