EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until
10000400560-PA-NA-CHN Rev.0.0	PRJN-189004-2020-PA-CHN	27 May 2024

This is to certify that the quality system of:

Shenzhen Ruiankang Technology Co., Ltd.

Floor 4, Building A, NO.10 Shibi Hongling Industrial Area, Liulian Community, Pingdi Street, Longgang District, Shenzhen

For design, production and final product inspection/testing of:

INFRARED THERMOMETER

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 09 March 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Sholeh Gheissar

Sholeh Gheissar
Principal assessor

Certificate No.: 10000400560-PA-NA-CHN Rev.0.0
Place and date: Høvik 09 March 2021

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	09 March 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Infrared thermometer	RAK-FI01, RAK-FI02, RAK-FI03, RAK-FI04, RAK-FI05	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Shenzhen Ruiankang Technology Co., Ltd.	Floor 4, Building A, NO.10 Shibi Hongling Industrial Area, Liulian Community, Pingdi Street, Longgang District, Shenzhen

EU Representative

Wellkang Ltd,
Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland, UK

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

APPENDIX TO EC CERTIFICATE

Certificate no.:
10000400560-PA-NA-CHN Rev.0.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
Shenzhen Ruiankang Technology Co., Ltd.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment and audit performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A relocated Company address, replacing the one stated on the certificate, has been accepted.

Site Name	Site Address
Shenzhen Ruiankang Technology Co., Ltd.	Floor 1 and 2, No.8, Zhugushi Chunyang Industrial Park, Wulian Community, Longgang Street, Longgang District, Shenzhen City, Guangdong, China

There are no changes to the certification to MDD, the basis for the certification nor the activities performed to maintain the certification.

The Accreditation with Norwegian Accreditation will cease from 01 Jan. 2022 and the accreditation mark has no validity.

Appendix History -		
Revision	**Description**	**Issued Date**
0.0	Removal of Norwegian Accreditation and change of company address	29 March 2022

Place and date:
Høvik, 29 March 2022

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer