

Number: 6127621CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Wenzhou Bokang Instruments Co., Ltd.

No.1099 Kunbei Road, Lingkun Street
Wenzhou Marine Economic Development Demonstration Zone
Wenzhou, 325026 Zhejiang Province
China

SRN ID.: CN-MF-000021505

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6127622CN

Authorized Representative:

Shanghai International Holding Corp. GmbH(Europe)
Eiffestraße, 80 20537 Hamburg, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Principal Certification Manager

First Issued: 25 July 2023

Date: 29 November 2024

Expiry date: 1 July 2028

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Active non-implantable devices for monitoring of vital physiological parameters (MDA0203, Class IIa)

Device Name:

- Infrared Forehead Thermometers
- Electronic Sphygmomanometers

Non-active non-implantable diagnostic devices (MDN1207, class Im)

Group of Devices:

- Aneroid Sphygmomanometers

Conditions for or limitations to the validity of this certificate:

- For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	25 July 2023	6127622CN02	first issue
1	15 September 2023	6127622CN03	revised
2	29 November 2024	6127622CN04	revised

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