**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. 1500 Haining Road, Haibin, Longwan**
**325024 Wenzhou, Zhejiang**
**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: **15 September 2023** Expiry date**: 1 July 2028**



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

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:**<br>- Infrared Forehead Thermometers<br>- Electronic Sphygmomanometers |

| **Non-active non-implantable diagnostic devices (MDN1207, class Im)** |
|---|
| **Group of Devices:**<br>- 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 |

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