# FISCAL YEAR 2020

## CERTIFICATE OF REGISTRATION

**This certifies that**

## HEBEI EVIDENCE-BASED MEDICAL TECHNOLOGY CO.,LTD

F/10, INNOVATION BUILDING, NO. 315, CHANGJIANG BOULEVARD, HIGH-TECH DEVELOPMENT ZONE

SHIJIAZHUANG CITY, HEBEI CHINA

**Has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through**

| Owner/Operator Number: 10067948 | | |
|---|---|---|
| **Listing Number** | **Product Code** | **Proprietary Name** |
| D387255 | FQZ | Infrared thermometer (X5, X6, X7, X8, X9, X10) |

**MTTZ will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. MTTZ makes no other representations or warranties, nor does this certificate make any representations or warranties to any person pr entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. MTTZ assumes no liability to any person or entity in connection with the foregoing.**

**Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misleading." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. MTTZ is not affiliated with the U.S. Food and Drug Administration.**

MTTZ CERTIFICATION

**Chief Engineer**

**Issue date: 07.04.2020**

**Expiration date: 31.12.2020**

# Attestation of Conformity

**No. ICR Polska/M7008920**

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|---|---|
| **Name and address of Registered Manufacturer:** | Hebei Evidence-based Medical Protective Products Co., Ltd.<br>Room 2303, Block A, Fortune Building, No. 86 Guang'an Street,<br>Chang'an District, Shijiazhuang City, Hebei Province |
| **Product name:** | Forehead thermometer |
| **Product type/model:** | X5, X6 |

**This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.**

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| **Relevant EC Directive:** | Medical Device Directive 93/42/EEC |
| **Conformity assessment procedure:** | EC Declaration of Conformity (Annex VII of Directive 93/42/EEC) |
| **Classification:** | Class I according Rule 1 of Annex IX of Directive 93/42/EEC |
| **Applied normative documents:** | EN 1041:2008+A1:2013<br>EN ISO 10993-1:2009+AC:2010<br>EN ISO 15223-1:2016<br>EN ISO 14971:2012 |
| **Applied Quality Management System** | EN ISO 13485:2016 |

This Attestation of Conformity will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by European Quality Test Co., LTD.

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| **No. of test report:** | TMHB20031222363 |
| **Issue date:** | 24.03.2020 |
| **Expiration date:** | 23.03.2025 |

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-7089.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.

INTERNATIONAL CERTIFICATION REGISTAR ICR REGISTERED FIRM JEDNOSTKA NOTYFIKOWANA Nr 2703

Director: Rafał Kalinowski

Warsaw, 24. 03. 2020.