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REVISION STATUS:

Version	Brief Description of Revision	Author	Date *(DD MMM YYYY)*
V1.0	First procedure	Taoying Li	2020-04-08
V1.1	Add the intended use and basic UDI-DI according to audit opinion.	Taoying Li	2020-05-18

EU Declaration of Conformity

Manufacturer: Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.
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SRN: To be registered

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SRN: To be registered

Product: Infrared forehead thermometer
Brand name: /
Intended use: Infrared forehead thermometer is an infrared thermometer intended for the measurement of human body temperature in people of all ages without contact to the body and may be used by medical professionals or by consumers in a home environment.
Basic UDI-DI: To be applied
Device Nomenclature Code: V03010102
Model List: See Annex 1
Applied Standards List: See Annex 2

Classification: According to Annex VIII, Rule 10 of (EU) 2017/745 (MDR), the Infrared forehead thermometer is in class IIa.

Conformity Assessment Route: Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex, Regulation (EU) 2017/745 (MDR)
We hereby declare that the above mentioned product meet the provisions of the Regulation (EU) 2017/745 (MDR) for medical devices. No medicinal product, including a medicinal product derived from human blood or human plasma, no tissues or cells of human origin or their derivatives, no CMR or endocrine-disrupting substances are incorporated into the device. All supporting documentation is retained under the premises of the manufacturer and Notified Body 2797, BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

CE 2797

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance System Certificate No.:	\	\	\

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer: Shenzhen LEPU Intelligent Medical Equipment Co., Ltd.

Signed for and on behalf of :

Name	**:**	**Qingjun Yi**
Function (Company)	**:**	**Management Representative**
Date	**:**	_____***DD/MM/YYYY***
Location	**:**	**Shenzhen**

Annex 1 Catalogue Number List

Table 1 Specifications of Infrared forehead thermometer

Model	Structure	Button	Size (length*width*height)	Power supply	Low voltage alarm	Mode	Automatic power off/standby	Memory group	Appearance
LFR30B	LFR30 series main structure	● On/Off Button ● Memory button ● Mode slide button	168.5mm*36mm*48mm	d.c.3V	When the voltage of LFR30B is lower than 2.5± 0.1V, the low-voltage symbol will appear after turning on, and it cannot be measured. The low-voltage symbol is “▼”	Body mode “” Calibration mode “”	The device is automatically turned off after 1min±10s when there is no operation	99 groups	
LFR50	LFR50 series main structure	● On/Off Button ● Memory button ● Mode button	132mm*42mm*173.5mm	d.c.9V	When the voltage of LFR50/60 is lower than 5.8±0.2V, the low-voltage symbol will appear after turning on, and it cannot be measured. The low-voltage symbol is “”	Body mode “” Calibration mode “” Room mode “”	The device automatically enters into standby status after 60s when there is no operation, and no further operation, it will shut down automatically in 60 minutes.	99 groups	

Model	Structure	Button	Size (length*width*height)	Power supply	Low voltage alarm	Mode	Automatic power off/standby	Memory group	Appearance
LFR60	LFR60 series main structure	● On/Off Button, ● Memory button ● Mode button	129mm*41.5mm*171mm	d.c.9V	When the voltage of LFR50/60 is lower than 5.8±0.2V, the low-voltage symbol will appear after turning on, and it cannot be measured. The low-voltage symbol is “ ”	Body mode “ ” Calibration mode “ ” Room mode “ ”	The device automatically enters into standby status after 60s when there is no operation, and no further operation, it will shut down automatically in 60 minutes.	99 groups	
Remarks	Different main structure	The LFR30B switches mode by sliding the mode slide button, and the LRF50/60 switches mode by pressing down the mode button	Different size	Different power supply	Due to the different power supply, the low voltage alarm is different, and the low-power symbol is also different.	LFR50/60 are equipped with an additional room mode compared with LFR30B, and the symbol of calibration mode and body mode is also different	LFR50/60 are equipped with an additional standby function compared with LFR30B.	The memory group of all three models is the same, but LFR50/60 will display the group number on the LCD in real time, while the LFR30B will not.	Different appearance

Accessories: There are two 1.5V AAA dry batteries packaged with the LFR30B, and one 9V dry battery packaged with LFR50/60.

Annex 2 Applied Standards/Common Specifications (CS) List

The standards/Common Specifications (CS) applicable for this product are listed as below:

Standard /Common Specifications (CS) No.	Standard/Common Specifications (CS) Name	Date of Issue	Full/Partial Compliance
EN 1041:2008+A1: 2013	Information supplied by the manufacturer of medical devices	2013-09-25	Full
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices	2012-07-31	Full
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016-11-30	Full
EN ISO 13485: 2016+AC:2018	Medical devices - Quality management systems- Requirements for regulatory purposes	2018-03-28	Partial Compliance
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices	2015-02	Partial Compliance
EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	2015-07	Full
IEC/TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	2016-04-27	Technical guidance
IEC 62304:2015	Medical device software - Software life-cycle processes	2015-06	Partial Compliance
IEC 60601-1:2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2012-08	Partial Compliance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2014-02	Full
IEC 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2015-01	Partial Compliance
ISO 80601-2-56:2017+AC:2018	Medical electrical equipment —Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	2018-11	Partial Compliance
EN ISO 14155:2011+AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice	2011-07-15	Full
MEDDEV 2.7/1 rev.4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	2016-06	Full
MEDDEV 2.12/1 rev.8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM	2013-01	Full
/	Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8	2019-06	Full
ISTA 2A-2011(2012)	International Safe Transport Association Transport Test Standard	2012-01	Full
IEC 62506:2013	Methods for product accelerated testing	2013-06	Partial Compliance