

EC CERTIFICATE

Annex II excluding section 4 of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number

CE-MDD-0061/04/2020/01

Manufacturer : Suzhou Melodicare Medical Technology Co., Ltd.

Address : Room 301, Building F2, No.32 Hongxi road, Suzhou high-tech zone, Jiangsu province, China

Product(s) : 1. Continuous Monitoring Thermometer
2. Dynamic ECG Monitor
3. Infrared Thermometer
4. Vital Signs Monitor

Model(s)	Product Name	Model Name
	Continuous Monitoring Thermometer	Coola
	Dynamic ECG Monitor	MCT-H1
	Infrared Thermometer	Breeze
	Vital Signs Monitor	Vision

Report Number : CE-MED-0061-01, CE-MED-0061-02,
CE-MED-0061-03, CE-MED-0061-04

First Issue Date and Place : 2020.05.05 & Istanbul

Revision Number and Date : 00 / --

Validity Date : 2024.05.26

NOTICE, Notified Body 2764, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits. NOTICE must be informed of any significant changes in the design and/or construction of the product(s).

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