

EC Certificate Production Quality Assurance System: Certificate CN19/41053

The management system of:

Dongguan SIMZO Electronic Technology Co., Ltd.

No.6, Zhangzhou Road, Daojiao Town, Dongguan City, Guangdong Province, 523187, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V For the following products

Infrared Thermometer used for measuring body temperature (Model: HW-1, HW-2, HW-2S, HW-3, HW-4, HW-4S, HW-302, HW-303, HW-F1, HW-F2, HW-F3, HW-F4, HW-F5, HW-F6, HW-F7); Portable (Ultrasonic) Nebulizer on Conscious Patients (NBM-1, NBM-2,

NBM-3, NBM-3B, NBM-4, NBM-4B, NBM-5, NBM-5B, NBM-6, NBM-6B, NBM-7, NBM-7B, NBM-8, NBM-8B); Clinical Digital Thermometer

(TH-801, TH-802, TH-803, TH-804, TH-805, TH-806, TH-807, TH-808, TH-809)

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 01 February 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits. Issue 3. Certified since 27 January 2015 and first certified by SGS Belgium NV since 16 December 2019 Certification is based on reports numbered CN/DGG/ 16426

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639

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