< EC 符合性声明>

EC Declaration of Conformity

We, Dong guan city Good health Electronic Technology CO.,LTD.

Address: 4 Floor, B Building Chang huang road, Qiaoli village, Changping town, Dong guan city

Tel：+86-0769-89303585 Fax: +86- 0769-81082885

Declare with sole responsibility, that our following products:

Digital blood pressure monitor (Wrist Type)

(HK-601,HK-602,HK-603,HK-605,HK-606,HK-607,HK-608,HK-609,HK-610,HK-611)

Digital blood pressure monitor (Arm type)

(HK-801,HK-802,HK-803,HK-805,HK-806,HK-807,HK-808,HK-809,HK-810,HK-811)

Electronic thermometer

(HK-901,HK-902,HK-903,HK-905,HK-906,HK-907,HK-908,HK-909,HK-910,HK-911)

meet the essential requirements of Council Directive 93/42/EEC & 2007/47/EC, pertaining to medical devices. We hereby appoint, ***CGI Business Trading and Consulting e.K, Hans-Bethe-Str.1, 60438 Frankfurt am Main, Germany,*** to act as our European Authorized Representative as explicitly defined in the above-mentioned Directive.

Signed this day 20th of Nov. ,2018, Place China

Represented by:

Title: General Manager

Name: Morgan

Signature:

Official Seal:

EC Certificate
Production Quality Assurance System

Certificate No.:	Project No.:	Valid until:
10095-2017-CE-RGC-NA-PS	PRJC-490771-2013-PRC-CHN	09 March 2020

This is to certify that the quality system of:

Dong Guan City Good Health Electronic Technology Co., Ltd.
4 Floor, B Building, Chang Huang Road, Qiaoli Village, Changping Town,
Dong Guan City, P.R. China

For production and final product inspection/testing of:

Electro Medical Devices

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.2.b and Annex V (Module D1) of Council Directive 93/42/EEC on Medical Devices, as amended
and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 6 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Production Quality Assurance System

Certificate No.: 10095-2017-CE-RGC-NA-PS
Project No.: PRJC-490771-2013-PRC-CHN
Valid until: 09 March 2020

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 5828-2015-CE-RGC-NA (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-11-06

Products covered by this Certificate:

Product Description	Product Name	Class
Digital Blood Pressure Monitor	HK-601, HK-602, HK-603, HK-605, HK-606, HK-607, HK-608, HK-609, HK-610, HK-611 HK-801, HK-802, HK-803, HK-805, HK-806, HK-807, HK-808, HK-809, HK-810, HK-811	IIa
Digital Thermometer	HK-901, HK-902, HK-903, HK-905, HK-906, HK-907, HK-908, HK-909, HK-910, HK-911	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Dong Guan City Good Health Electronic Technology Co., Ltd.,

4 Floor, B Building, Chang Huang Road, Qiaoli Village, Changping Town, Dong Guan City, P.R. China

EC Certificate
Production Quality Assurance System

Certificate No.:	Project No.:	Valid until:
10095-2017-CE-RGC-NA-PS	PRJC-490771-2013-PRC-CHN	09 March 2020

EU Representative

CGI Business Trading and Consulting, Inh. Herr Leizhang, Huegel Str. 73, 60433 Frankfurt am Main, Germany

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate