TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
Österreich

has established and applies a quality management system for medical devices for the following scope:

Design and development, manufacturing and distribution of blood pressure monitors and non-active medical devices for injection and infusion and pricking devices as well as in vitro diagnostic devices for self-testing

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Digitally signed by Captari Vladimir
Date: 2021.03.20 16:22:43 EET
Reason: MoldSign Signature
Location: Moldova

Effective Date:	2019-05-02
Certificate Registration No.:	SX 60138807 0001
An audit was performed. Report No.:	21246563 019
This Certificate is valid until:	2022-05-01

Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2019-04-29

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60141729 0001

Report No.: 21246563 023

Manufacturer:
MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
Österreich

Products: (see attachment for products included)

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-09-24

Date: 2019-09-24

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60141729 0001
Report No.: 21246563 023

Manufacturer: MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
Österreich

Products included:

- Disposable Syringes
- Blood Lancets
- Hypodermic Needles
- Electronic Blood Pressure Monitors

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2019-09-24

Dipl.-Ing. I. Munkler

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen Pango Electronic Co., Ltd.
No. 25, 1st Industry Zone
Fenghuang Road, Xikeng Village
Henggang Town, Longgang District
Shenzhen
518115 Guangdong
China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices
(see attachment for products and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2019-03-27
Certificate Registration No.:	SX 60131968 0001
An audit was performed. Report No.:	17061667 005
This Certificate is valid until:	2021-11-09

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
III
Zertifizierstelle

Date 2019-03-27

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60131968 0001
Report No.: 17061667 005

Organization:
Shenzhen Pango Electronic Co., Ltd.
No. 25, 1st Industry Zone
Fenghuang Road, Xikeng Village
Henggang Town, Longgang District
Shenzhen
518115 Guangdong
China

Scope:

Products:

- Intermittent pneumatic compression units
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear/Forehead Thermometers

Site included:

2-4 Floor, No.5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China

Manufacture of Intermittent pneumatic compression units, Infrared Ear Thermometers, Infrared Forehead Thermometers, Infrared Ear/Forehead Thermometers

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2019-03-27

S. Liu

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60146953 0001

Report No.: 17061667 011

Manufacturer:

Shenzhen Pango Electronic Co., Ltd.
No. 25, 1st Industry Zone
Fenghuang Road, Xikeng Village
Henggang Town, Longgang District
Shenzhen
518115 Guangdong
P.R. China

Products:

Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60129178 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-02-18

Date: 2020-02-18

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146953 0001
Report No.: 17061667 011

Manufacturer:
Shenzhen Pango Electronic Co., Ltd.
No. 25, 1st Industry Zone
Fenghuang Road, Xikeng Village
Henggang Town, Longgang District
Shenzhen
518115 Guangdong
P.R. China

Products:

- Intermittent pneumatic compression units
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear/Forehead Thermometers

Site included:

2-4 Floor, No.5 Shanzhuang Rd., Xikeng Village,
Henggang Town, Longgang District, Shenzhen City,
Guangdong Province, China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2020-02-18

Jing Zhang

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:	**Shenzhen Pango Electronic Co., Ltd.** **No.25, 1st Industry Zone, Fenghuang Road, Xikeng Village, Henggang Town, Longgang District, Shenzhen, Guangdong, 518115, China**
European Authorized Representative info. :	**Lotus NL B.V.** **Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.** **Tel : +31645171879 (English), +31626669008 (Dutch)**

We declare under our sole responsibility that

the medical device:	**Infrared Ear Thermometer, model: PG-IRT1601;** **Infrared Forehead Thermometer, model: PG-IRT1602;** **Infrared Ear/Forehead Thermometer, model: PG-IRT1603**
UMDNS CODE :	**17887 Thermometers, Infrared, Ear**
UMDNS CODE :	**17888 Thermometers, Infrared, Skin**
Of class: /	**Class IIa, rule 10**

According to annex IX of directive 93/42/EEC

Meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: /	**Directive 93/42/EEC Annex II, excluding Section 4**
Registration No.:	**HD 60146953 0001**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen / 2020-04-10

Place, date /

President Li Hui Jun

Name and function

深圳市泛谷电子有限公司
Shenzhen Pango Electronic Co., Ltd.

wellion®

DIABETES - UND GESUNDHEITS PRODUKTE
DIABETES AND HEALTH PRODUCTS

AUSTRIA

wellion®

Infrarot Stirn- und Ohr-Thermometer
Infrared Forehead and Ear Thermometer

KONTAKTLOSE MESSUNG
CONTACTLESS MEASUREMENT

OBJEKTTEMPERATUR-MESSUNG
OBJECT TEMPERATURE MEASUREMENT

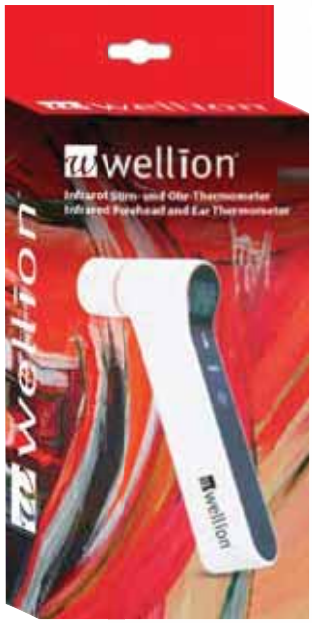
1 SEKUNDE MESSDAUER
1 SECOND TESTING TIME

9 SPEICHERWERTE
9 RESULTS IN MEMORY

GENAUIGKEIT: (35,0°C - 42,0°C) ± 0,2°C
ACCURACY: (35,0°C - 42,0°C) ±0,2°C

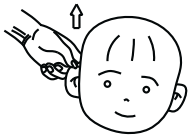
MESSBEREICH: 34,0°C BIS 43,0°C
MEASURING RANGE: 34,0°C - 43,0°C

2X AAA BATTERIEN
2X AAA BATTERIES



Art.Nr. WELL15-03
PhzNr AT: 5174093, PhzNr DE: 15870014

Vorstellen der Messmethoden
Introduction of Measurement methods

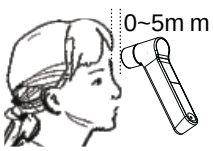


Ziehen Sie die Ohrläppchen bei Kindern unter einem Jahr leicht zurück.
Please pull nack ears of your kid who is within one year old.

Ohrtemperatur
Ear temperature

Ziehen Sie die Ohren nach oben zurück (bei Kindern älter als ein Jahr und Erwachsenen)
Please pull these persons' ears back above. (over one year old kids and adults)

Ohrtemperatur
Ear temperature



Mitte der Stirn
The center of forehead

Stirntemperatur
Forehead temperature

wellion®
WAVE

HINTERGRUNDBELEUCHTETES DISPLAY
BACKLIT DISPLAY

WHO BLUTDRUCK KLASSIFIZIERUNG
WHO BLOOD PRESSURE CLASSIFICATION

GROSSE, GUT LESBARE ZIFFERN
LARGE, CLEAR DIGITS

90 SPEICHERWERTE
90 RESULTS IN MEMORY

UNIVERSELLE UNTERARM-MANSCHETTENGRÖSSE 13,5-19,5 CM
UNIVERSAL WRIST CUFF SIZE 13,5-19,5 CM

UNIVERSELLE OBERARM-MANSCHETTENGRÖSSE 22-42 CM & 22-52CM
UNIVERSAL UPPER ARM CUFF SIZE

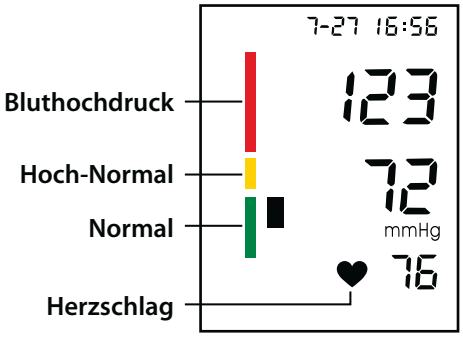
Wellion WAVE Blutdruckmessgeräte verwenden die oszillometrische Methode zur Bestimmung des Blutdrucks.

Die Produkte erfüllen die Anforderungen zur elektromagnetischen Kompatibilität der EN60601-1-2 und die Sicherheitsstandards der EN60601-1, sowie die Leistungskriterien der IEC 80601-2-30, spezifiziert in der EEC Direktive 93/42/EEC

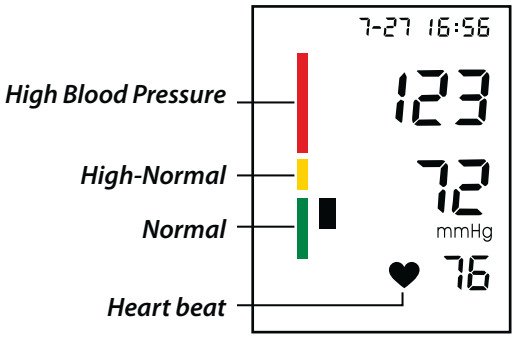
The Wellion WAVE Blood Pressure Monitors use the oscillometric method of blood pressure measurement.

The products comply with the electromagnetic compatibility requirements of EN 60601-1-2 and safety standards of EN 60601-1 and performance of IEC 80601-2-30 as specified in EEC directive 93/42/EEC.

WHO Blutdruck Klassifizierung
bei beiden Geräten



WHO Blood Pressure classification
on both devices



wellion®

AUSTRIA

Ihre ÖSTERREICHISCHE Gesundheitsmarke
Your AUSTRIAN health brand

Unser Bestreben ist es, Patienten und Partnern das Leben zu erleichtern.
Mit innovativen Ideen, Beratung und Service.

We endeavour to make life easier for patients and partners.
Through innovative ideas, advice and service.

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www.medtrust.at • www.wellion.at

MED TRUST
THE MEDICAL SERVICES COMPANY

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e-mail: office@medtrust.de
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WEL110DE_EN-2019-11