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: 2021.09.23 10:37:30 EEST
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 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60146513 0001

Report No.: 21246563 019

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

Products:
In-vitro-Diagnostic Monitoring Systems for Self-Testing

(see attachment for products included)
Replaces Certificate, Registration No.: HL 60110343 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC 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 IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2020-08-21

Date: 2020-08-21

Notified Body

Katja Mierisch

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic 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.: HL 60146513 0001
Report No.: 21246563 019

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

Products included:

- Blood Glucose Meters
- Blood Glucose and Cholesterol Meters
- Blood Glucose and Ketone Meters
- Blood Glucose, Cholesterol and Uric Acid Meters
- Glucose Control Solutions
- Cholesterol Control Solutions
- Ketone Control Solutions
- Uric Acid Control Solutions
- Glucose Test Strips
- Cholesterol Test Strips
- Ketone Test Strips
- Uric Acid Test Strips

Date: 2020-08-21

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch

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.

Hersteller/Manufacturer:
MED TRUST Handelsges.m.b.H.
Gewerbepark 10
7221 Marz
AUSTRIA

Produktspezifikation / Product details:

Artikelnummer / Article number Medizinprodukt / Medical device	WELL610	Wellion LUNA GLU test strips 10ct
	WELL612	Wellion LUNA GLU test strips 25ct
	WELL615	Wellion LUNA GLU test strips 50ct
	WELL614_F	Wellion LUNA GLU test strips 1ct foil
	WELL610_F	Wellion LUNA GLU test strips 10ct foil
	WELL612_F	Wellion LUNA GLU test strips 25ct foil
	WELL615_F	Wellion LUNA GLU test strips 50ct foil
	WELL610CHOL	Wellion LUNA CHOL test strips 10ct
	WELL611CHOL	Wellion LUNA CHOL test strips 5ct
	WELL612CHOL	Wellion LUNA CHOL test strips 25ct
	WELL610UA	Wellion LUNA UA test strips 10ct
	WELL612UA	Wellion LUNA UA test strips 25ct
Klassifikation nach / Classification according	Annex II, List B, Self testing	
Umfang / Scope	Diese Konformitätserklärung gilt ausschließlich in Verbindung mit einem chargenbezogenen Freigabedokument. This Declaration of Conformity applies only in conjunction with a batch-related release document.	

Konformitätsbewertung / Assessment details:

Benannte Stelle / Notified body	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Deutschland
Verfahren nach / Procedure according to	IVDD 98/79/EC, Annex IV, excluding section 4 and 6
Zertifikate/ Certificates	HL 60146513 0001

Harmonisierte Normen / Harmonized standards **Aktueller Stand per / Current status per: 01.09.2020**

<Nummer und Ausgabejahr> / <Number and version year>

EN ISO 13485:2016, EN 13532:2002, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13975:2003, EN ISO 14971:2012, EN ISO 15197:2015, EN ISO 15223-1:2016, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 18113-4:2011, EN ISO 18113-5:2011, EN ISO 18153:2003

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EC und deren Umsetzungen in nationale Gesetze entsprechen. Die Produkte werden mit CE-Kennzeichnung versehen.
Die Produkte entsprechen den anzuwendenden Normen in der jeweils gültigen Form.

Gültig ab:	07.08.2020	**KONFORMITÄTSERKLÄRUNG** **DECLARATION OF CONFORMITY**	MED TRUST THE MEDICAL SERVICES COMPANY
Revisionsnr.	03		
Erstellt	MIT		
Geprüft	FEI	**RG0005**	
Freigegeben	FEI		
Seite:	Seite 2 von 2		
Vertraulichkeit:		Dieses Dokument und jede enthaltene Information sind Eigentum der Firma MED TRUST Handelsgesellschaft m.b.H.	

We declare under sole responsibility that the products described above meet the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The products are CE marked.
The products comply with the applicable standards in its actual version.

CE 0197

Gültig bis / Valid until: 26.05.2024

Marz, 1.09.2020
Ort, Datum / Place, Date

MED TRUST HANDELSGES.M.B.H.
A-7221 MARZ, GEWERBEPARK 10
TEL.: 02626/64190 FAX: 02626/64190-77
Dr. Andrea Feiler
Quality Management Department

Gültig ab:	01.07.2019
Revisionsnr.	02
Erstellt	FEI
Geprüft	FIG
Freigegeben	FEI
Seite:	Seite 1 von 1
Vertraulichkeit:	

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

MED TRUST
THE MEDICAL SERVICES COMPANY

Produktspezifikation / Product details:

Artikelnummer / Article number	WELL670	Wellion LUNA GLU control solution 0
Medizinprodukt / Medical device	WELL675	Wellion LUNA GLU control solution 1
	WELL680	Wellion LUNA GLU control solution 2
	WELL675CHOL	Wellion LUNA CHOL control solution 1
	WELL680CHOL	Wellion LUNA CHOL control solution 2
	WELL675UA	Wellion LUNA UA control solution 1
Klassifikation nach / Classification according	Annex II, List B, Self testing	
Umfang / Scope	Diese Konformitätserklärung gilt ausschließlich in Verbindung mit einem chargenbezogenen Freigabedokument. This Declaration of Conformity applies only in conjunction with a batch-related release document.	

Konformitätsbewertung / Assessment details:

Benannte Stelle / Notified body	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg
Verfahren nach / Route of directive	98/79/EC, Annex IV section 3
Zertifikate/ Certificates	HL 60110343 0001

Harmonisierte Normen / Harmonized standards **Aktueller Stand per / Current status per: 13.02.2020**

EN ISO 13485:2016/AC:2016, EN 13532:2002, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13975:2003, EN ISO 14971:2012, EN ISO 15197:2015, EN ISO 15223-1:2016, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 18113-4:2011, EN ISO 18113-5:2011, EN ISO 18153:2003

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EC und deren Umsetzungen in nationale Gesetze entsprechen. Die Produkte werden mit CE-Kennzeichnung versehen.
Die Produkte entsprechen den anzuwendenden Normen in der jeweils gültigen Form.
We declare under sole responsibility that the products described above meet the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The products are CE marked.
The products comply with the applicable standards in its actual version.

CE 0197

Gültig bis / Valid until: 01.05.2021

MED TRUST HANDELSGES.M.B.H.
A-7221 MARZ, GEWERBEPARK 10
TEL.: 02626/64190, FAX: 02626/64190-77

Marz 13.02.2020
Ort, Datum / Place, Date

Ulrike Mitteregger
Quality Management

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

MED TRUST
THE MEDICAL SERVICES COMPANY

Produktspezifikation / Product details:

Artikelnummer / Article number Medizinprodukt / Medical device	WELL600DW	Wellion LUNA duo white mg Software Version BKM-13-6-Y
	WELL600DWMM	Wellion LUNA duo white mmol Software Version BKM-13-6-Y
	WELL600DB	Wellion LUNA duo black mg Software Version BKM-13-6-Y
	WELL600DBMM	Wellion LUNA duo black mmol Software Version BKM-13-6-Y
	WELL600DP	Wellion LUNA duo pink mg Software Version BKM-13-6-Y
	WELL600DPMM	Wellion LUNA duo pink mmol Software Version BKM-13-6-Y
	WELL600DY	Wellion LUNA duo yellow mg Software Version BKM-13-6-Y
	WELL600DYMM	Wellion LUNA duo yellow mmol Software Version BKM-13-6-Y
	WELL600TW	Wellion LUNA trio white mg Software Version V621
	WELL600TWMM	Wellion LUNA trio white mmol Software Version V621
	WELL600TB	Wellion LUNA trio black mg Software Version V621
	WELL600TBMM	Wellion LUNA trio black mmol Software Version V621
	WELL600TP	Wellion LUNA trio pink mg Software Version V621
	WELL600TPMM	Wellion LUNA trio pink mmol Software Version V621
	WELL600TY	Wellion LUNA trio yellow mg Software Version V621
	WELL600TYMM	Wellion LUNA trio yellow mmol Software Version V621
Klassifikation nach / Classification according	Annex II, List B, Self-testing	
Umfang / Scope	Diese Konformitätserklärung gilt ausschließlich in Verbindung mit einem chargenbezogenen Freigabedokument. This Declaration of Conformity applies only in conjunction with a batch-related release document.	

Konformitätsbewertung / Assessment details:

Benannte Stelle / Notified body	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg
Verfahren nach / Route of directive	98/79/EC, Annex IV section 3
Zertifikate/ Certificates	HL 60110343 0001

KONFORMITÄTSERKLÄRUNG
DECLARATION OF CONFORMITY

MED TRUST
THE MEDICAL SERVICES COMPANY

Harmonisierte Normen / Harmonized standards **Aktueller Stand per / Current status per: 29.07.2020**

EN ISO 13485:2016 EN 13532:2002, EN 13612:2002/AC:2002, EN ISO 23640:2015, EN 13975:2003, EN ISO 14971:2012, EN ISO 15197:2015, EN ISO 15223-1:2016, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 18113-4:2011, EN ISO 18113-5:2011, EN 62366:2008, EN ISO 18153:2003

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EC und deren Umsetzungen in nationale Gesetze entsprechen. Die Produkte werden mit CE-Kennzeichnung versehen.
Die Produkte entsprechen den anzuwendenden Normen in der jeweils gültigen Form.
We declare under sole responsibility that the products described above meet the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The products are CE marked.
The products comply with the applicable standards in its actual version.

CE 0197

Gültig bis / Valid until: 01.05.2021

Marz, 29.07.2020
Ort, Datum / Place, Date

MED TRUST
Ulrike Mitteregger
Quality Management
MED TRUST HANDELSGES.M.B.H.
A-7221 MARZ; GEWERBEPARK 10
TEL.: 02626/64190; FAX: 02626/64190-77

Product Description of Wellion WAVE and Wellion WAVE professional blood pressure meters

Rev. No.: 00

Date: 10.09.2019

Approved: MIT

Products	Article numbers — Names WELLWAVE003 — Wellion WAVE WELLWAVE003P — Wellion WAVE professional
Product group	Blood pressure monitor

General description of the product:

Wellion WAVE (wrist type) and Wellion WAVE professional (upper arm type) blood pressure monitors are automatic non-invasive blood pressure meters.

Functional description:

The blood pressure monitors conduct inflation, deflation and measurement systolic and diastolic blood pressure and pulse rate of adult's wrist or upper arm are measured using the oscillometric technique within the specified range and accuracy.
The devices cannot measure continuously and thus measure only once by switching on and off. The devices also has low voltage indication, which will be triggered when the battery is low. The device has a data storage function in order for data reviewing, which can save 60 measurement records, including the systolic blood pressure, diastolic blood pressure, pulse rate and measurement time.

Specifications:

Wellion WAVE and Wellion WAVE professional provide a LCD display, memory function, time information and a WHO blood pressure classification.

Wellion WAVE is operating with two 1,5V batteries (LR03 or AAA), Wellion WAVE professional s operating with four 1,5V batteries (LR03 or AAA)

- Measuring range: pressure: 30-280 mmHg / 4-37,7kPa
  pulse: 40-199 beats / minute
- Accuracy: static pressure: +/- 3 mmHg / +/- 0,4 kPa
  pulse: +/- 5%
- Memory: 90 memories
- Conditions: the operating temperature of the devices are 5°C to 40°C at a relative humidity of 15% to 93% and an atmospheric pressure of 70 to 106 kPa. The storage condition are -20°C to +55°C, 0% - 93% relative humidity and an atmospheric pressure of 50 to 106 kPa.

- Diameter of wrist: 13,5 - 19,5 cm
- Diameter of upper arm: 22 - 42 cm

Conformity assessment route:

MDD 93/42/EEC, Annex V

Product classification:

Wellion WAVE and Wellion WAVE professional blood pressure monitors are classified according to Directive 93/42/EEC, as medical devices class IIa, Rule 6.

UMDNS/GMDN/EDMA/CND code:

Product	GMDN code			
Wellion WAVE	45617			
Wellion WAVE professional	45617			

Intended use:

The Wellion WAVE and Wellion WAVE professional blood pressure monitors are intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse on adults, with the cuff around the wrist or the upper arm.

Accessories

The cuff and the AC adapter are separate accessories optionally used for the Wellion WAVE professional. The cuff of the Wellion WAVE (wrist type) cannot be separated.

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MED TRUST HANDELSGES.M.B.H.
A-7221 MARZ; GEWERBEPARK 10
TEL: 02626/64190, FAX: 02626/64190-77

Gültig ab:	11.04.2019	**KONFORMITÄTSERKLÄRUNG** **DECLARATION OF CONFORMITY**	MED TRUST THE MEDICAL SERVICES COMPANY
Revisionsnr.	02		
Erstellt	FEI		
Geprüft	FIG	**RG0043**	
Freigegeben	FEI		
Seite:	Seite 1 von 2		
Vertraulichkeit:		Dieses Dokument und jede enthaltene Information sind Eigentum der Firma MED TRUST Handelsgesellschaft m.b.H. und sind ausschließlich **zur internen Verwendung** bestimmt.	

Produktspezifikation / Product details:

Artikelnummer / Article number Medizinprodukt / Medical device	WELLWAVE003	Wellion WAVE Software Version 2.5
	WELLWAVE003P	Wellion WAVE professional Software Version 2.5
	WELLWAVE021P	Wellion WAVE professional arm cuff
Klassifikation nach / Classification according	Annex IX, Class IIa, Rule 6	
Umfang / Scope	Diese Konformitätserklärung gilt ausschließlich in Verbindung mit einem chargenbezogenen Freigabedokument. This Declaration of Conformity applies only in conjunction with a batch-related release document.	

Konformitätsbewertung / Assessment details:

Benannte Stelle / Notified body	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg
Verfahren nach / Route of directive	MDD 93/42/EEC, Anhang V
Zertifikate/ Certificates	DD 60141729 001

Harmonisierte Normen / Harmonized standards **Aktueller Stand per / Current status per: 25.03.2020**

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, IEC 60601-1:2005/A1:2012, EN 1060-3:1997/A2:2009, IEC ISO 80601-2-35:2009, EN 60601-1-2:2015, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, IEC 60601-1-11:2010, EN 62366:2008, IEC 60601-1-6:2010, EN 62304:2006/AC:2008 , EN 1060-4:2004, EN ISO 14155:2011

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entsprechen. Die Produkte werden mit CE-Kennzeichnung versehen.
Die Produkte entsprechen den anzuwendenden Normen in der jeweils gültigen Form.
We declare under sole responsibility that the products described above meet the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The products are CE marked.
The products comply with the applicable standards in its actual version.

CE 0197

Gültig bis / Valid until: 26.05.2024

25.03.2020
Ort, Datum / Place, Date

MED TRUST HANDELSGES.M.B.H.
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TEL: 02626/64190; FAX: 02626/64190-77
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wellion®

DIABETES - UND GESUNDHEITS PRODUKTE
DIABETES AND HEALTH PRODUCTS

AUSTRIA

wellion®

Ihre ÖSTERREICHISCHE Gesundheitsmarke
Your AUSTRIAN Health Brand

Durch unseren persönlichen Kontakt zu Menschen mit Diabetes wissen wir, welche Wünsche und Bedürfnisse im Alltag bestehen um das Leben mit Diabetes optimal gestalten zu können. Unter der Marke Wellion stehen unseren Kunden zahlreiche Qualitätsprodukte, die speziell für Diabetiker entwickelt wurden, zur Verfügung. Bei der Entwicklung unserer Produkte setzen wir auf laufendes und umfassendes Qualitätsmanagement. Die EN ISO 13485:2016 Norm ist die Basis für unsere hochwertigen und innovativen Produkte der Marke Wellion.

Through our personal contact to people with diabetes we know their needs and wants regarding their daily routine - it is our goal to make their life with diabetes easier.
Under the brand Wellion we provide numerous quality products to our customers that are specially designed for diabetics. When developing our products we focus on ongoing and comprehensive quality management. The EN ISO 13485:2016 norm is the basis for high-quality and innovative Wellion products.

EN ISO 15197:2015

Die Wellion® Geräte erfüllen alle Kriterien der neuen EN ISO 15197:2015

The Wellion® devices fulfill all criteria of the new EN ISO 15197:2015

Wir sind laufend bemüht, die Wellion Linie um neue, innovative Produkte zu erweitern.

We constantly strive to expand the Wellion product line with new, innovative products.

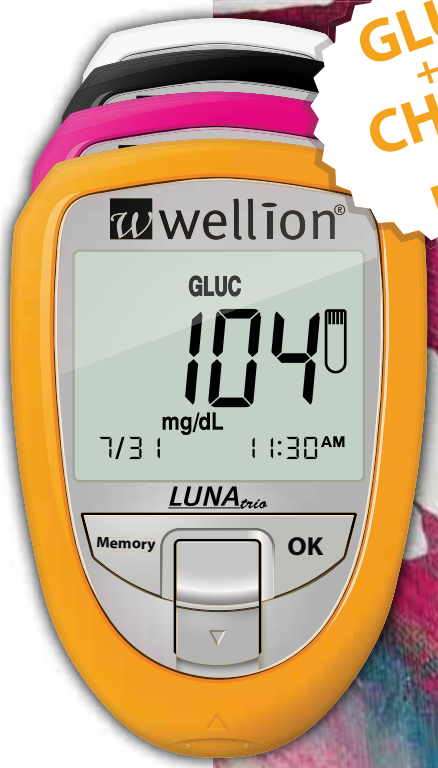
wellion LUNA trio	wellion GALILEO GLU/KET	wellion GALILEO GLU/CHOL	wellion GALILEO compact
✓	✓		✓
✓	-	✓	-
-	✓	-	-
5 GLU, 26 CHOL 15 Harnsäure / *Uric Acid*	5 GLU 8 KET	5 GLU 90 CHOL	5
0,5 µl GLU, 0,8 µl CHOL 1,0 µl Harnsäure / *Uric Acid*	0,5 µl GLU 0,8 µl KET	0,5 µl GLU 3,6 µl CHOL	0,5 µl
GOD	GOD		GOD
✓	✓		✓
-	✓		-
-	✓		-
✓	✓ Plus-Version		-
-	-		-
-	✓		-
-	✓		-
360 GLU, 50 CHOL 50 Harnsäure / *Uric Acid*	500 GLU 100 KET	500 GLU 100 CHOL	300
7, 14, 21, 28 - GLU	1, 7, 14, 30, 60, 90 - GLU		7, 14, 30
-	3 GLU, 3 KET	3 GLU, 3 CHOL	3
Dose / *vial*	GLU - Dose / *vial* KET - Folie / *foil*	GLU - Dose / *vial* CHOL - Folie / *foil*	Dose / *vial*
9 Monate / *months*	12 Monate / *months*		12 Monate / *months*
-	-		-

LUNA
1 Gerät - 3 Messwerte
1 meter - 3 parameters

GALILEO
3 Geräte - 1 GLU Teststreifen
3 meters - 1 GLU test strip

wellion
LUNA *trio*

GLU, CHOL & UA



Drei Werte in ansprechendem Design

- Misst Blutzucker, Cholesterin und Harnsäure
- Handliche Form und gut lesbares Display
- Mit Auswurftaste für benutzte Teststreifen
- Anti-Rutsch-Noppen
- Alle Messwerte werden automatisch gespeichert und lassen sich einfach abrufen

Three values in an appealing design

- *Measures Blood Glucose, Cholesterol and Uric Acid*
- *Handy shape and easy to read display*
- *With eject button for used test strips*
- *Anti-slip nubs*
- *All readings are stored automatically and are easy to recall*

Wellion LUNA Glukose Teststreifen / *glucose test strips*

Inhalt / *Content*	Artikelnummer/ *Article number*	PhzNr AT	PhzNr DE
10 Stk	WELL610	4041042	00865680
50 Stk	WELL615	4041059	00865697

Wellion LUNA Cholesterin Teststreifen / *cholesterol test strips*

Inhalt / *Content*	Artikelnummer/ *Article number*	PhzNr AT	PhzNr DE
5 Stk	WELL611CHOL	4097396	04857683
10 Stk	WELL610CHOL	4041065	00866053

Wellion LUNA Harnsäure Teststreifen / *uric acid test strips*

Inhalt / *Content*	Artikelnummer/ *Article number*	PhzNr AT	PhzNr DE
10 Stk	WELL610UA	5210883	16151712

Die Wellion® LUNA Trio Blutzuckermessgeräte erfüllen alle Kriterien der neuen EN ISO 15197:2015.

The Wellion® LUNA Trio Blood Glucose Meters fulfill all criteria of the new EN ISO 15197:2015.

- GROSSE, GUT LESBARE ZIFFERN
  LARGE, CLEAR DIGITS
- AUSWURFTASTE
  EJECT BUTTON
- DURCHSCHNITTSWERTE
  AVERAGES
- 1000 MESSUNGEN BATTERIELEBENSDAUER
  1000 TESTS BATTERY LIFE
- 1x CR2032 BATTERIEN
  1X CR2032 BATTERIES
- USB-ANSCHLUSS
  USB-CONNECTION

BLUTZUCKER *BLOOD GLUCOSE*

- KEIN KODIEREN
  NO CODE
- 5 SEKUNDEN MESSDAUER
  5 SECONDS TESTING TIME
- 360 SPEICHERWERTE
  360 RESULTS IN MEMORY
- 0,5 MIKROLITER BLUT
  0,5 MICRO LITER BLOOD

CHOLESTERIN *CHOLESTEROL*

- CODE-STREIFEN
  CODE-STRIP
- 26 SEKUNDEN MESSDAUER
  26 SECONDS TESTING TIME
- 50 SPEICHERWERTE
  50 RESULTS IN MEMORY
- 0,8 MIKROLITER BLUT
  0,8 MICRO LITER BLOOD

HARNSÄURE *URIC ACID*

- CODE-STREIFEN
  CODE-STRIP
- 15 SEKUNDEN MESSDAUER
  15 SECONDS TESTING TIME
- 50 SPEICHERWERTE
  50 RESULTS IN MEMORY
- 1,0 MIKROLITER BLUT
  1,0 MICRO LITER BLOOD

LUNA *trio*

wellion®
LANCETS

Lanzetten sind Einmalprodukte!
Do not reuse lancets!

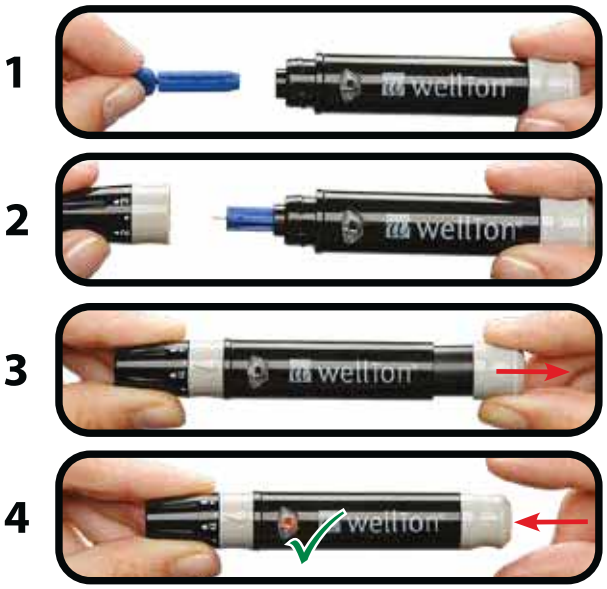
Perfekter Schliff für eine sanfte Blutgewinnung

- Sterile Lanzette
- Ultrafeine Nadel für geringes Schmerzempfinden
- In zwei Nadelstärken erhältlich (28G, 33G)
- 33G Lanzette zur Blutgewinnung speziell bei Kindern und empfindlichen Personen geeignet

Perfect cut for gentle blood sampling

- *Sterile lancet*
- *Ultra-fine needle minimizes pain*
- *In two different needle sizes (28G, 33G) available*
- *Super fine 33G lancet and therefore optimal for children and people with very sensitive skin.*

2,5-fach vergrößerte Darstellung des Durchmessers
Diameter zoomed 2,5-times.



Nadelstärke *needle size*	Inhalt *content*	Art.Nr.	PhzNr AT	PhzNr DE
28G	50 Stk	WELL250	3144691	05014202
	100 Stk	WELL208	3387471	05485491
	200 Stk	WELL200	2480079	05014225
33G	50 Stk	WELL253	3144716	05014171
	100 Stk	WELL207	3387502	05485516
	200 Stk	WELL203	3144722	05014194

wellion®

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

KONTAKTLOSE MESSUNG
CONTACTLESS MEASUREMENT

OBJEKTTEMPERATUR-MESSUNG
OBJECT TEMPERATURE MEASUREMENT

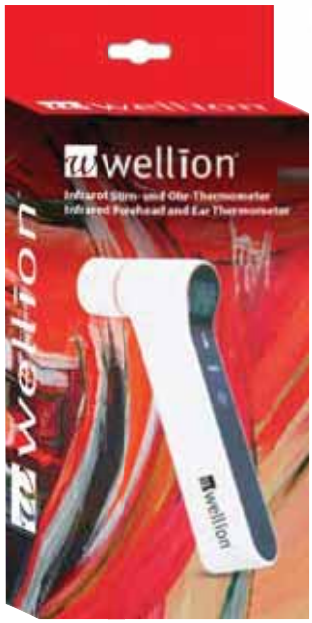
1 SEKUNDE MESSDAUER
1 SECOND TESTING TIME

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

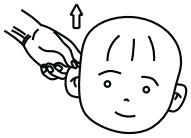
MESSBEREICH: 34,0°C BIS 43,0°C
MEASURING RANGE: 34,0°C - 43,0°C

2X AAA BATTERIEN
2X AAA BATTERIES



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

Vorstellen der Messmethoden
Introduction of Measurement methods

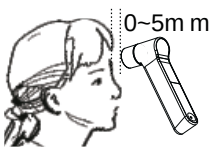


Ziehen Sie die Ohrläppchen bei Kindern unter einem Jahr leicht zurück.
Please pull nack ears of your kid who is within one year old.

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

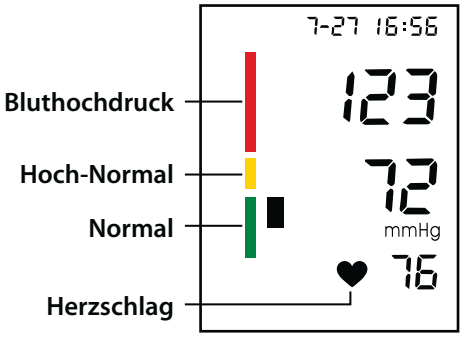
Wellion WAVE Blutdruckmessgeräte verwenden die oszillometrische Methode zur Bestimmung des Blutdrucks.

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

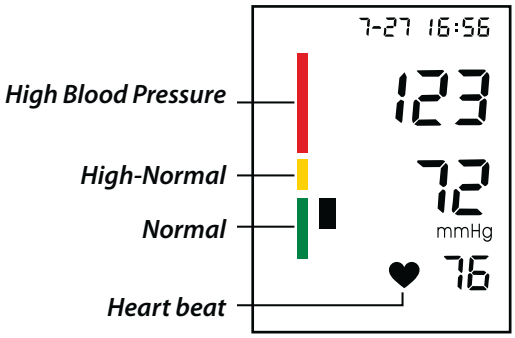
The Wellion WAVE Blood Pressure Monitors use the oscillometric method of blood pressure measurement.

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

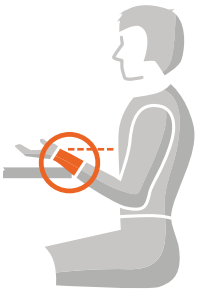


WHO Blood Pressure classification
on both devices



wellion® WAVE

Handgelenkgerät
Wrist Type



Art.Nr. WELLWAVE003
PhzNr AT: 4392557; PhzNr DE: 11563947

Beleuchtetes Display mit extra großen Ziffern
Backlit dispaly with large and clear digits

wellion® WAVE *professional*

Oberarmgerät
Upper Arm Type

Oberarmmanschette
praktisch verstaut
Upper arm cuff
practically stored

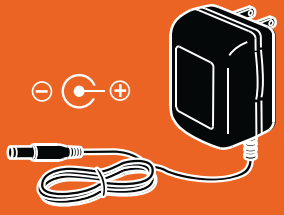
Messung beim Aufpumpen
Measure while inflating

Art.Nr. WELLWAVE003P
PhzNr AT: 4392563; PhzNr DE: 11563953

WAVE

Oberarmmanschette
22-42 cm & 22-52 cm
Upper arm cuff
22-42 cm & 22-52 cm
Art.Nr. WELLWAVE021P
& WELLWAVE021PXL

AC - Adapter
AC - Adapter
Art.Nr. WELLWAVE022P



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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