HERITAGE MEDICAL

Analizator składu ciała ACCUNIQ

Deklaracja zgodności i certyfikaty jakości

EC Declaration of Conformity

Manufacturer:
SELVAS Healthcare, Inc.
155, Shinseong-ro, Yuseong-gu, Daejeon,
34109 Republic of Korea

We, the manufacturer, herewith declare that the products

Body Composition Analyzer
Model: ACCUNIQ BC300
UMDNS-Code: **17417**
S/N: AP000264,265,267,268-20181128 (total 4 product)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa(body composition analyzer) according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Country : Germany
Certificate No.: DD 60125185 0001
Expiry date: 25.11.2020

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: SELVAS Healthcare, Inc.
Address: 155, Shinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea
Factory: 155, Shinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea

Daejeon, 01, JUL 2019
Place, date

Jin-Kyu Baek /QMR
Legally binding signature, Function

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

SELVAS Healthcare, Inc.
Mr. Tae-Gyu Choi
155, Shinseong-ro, Yuseong-gu
DAEJEON 34109
REPUBLIC OF KOREA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date December 22, 2017

Application for : **QMS Produktion, Anhang V MDD**
Certificate No. : DD 60125185 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Mr. Choi,

An Extraordinary audit of your quality management system to cover address change of certificate holder was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above mentioned requirements.

Enclosed please find the new certificate No. DD 60125185 0001 replacing the previous certificate, DD 60114162 0001.

With issue date of the new certificate, the previous certificate has become invalid.

Kind regards

Certification body

M.Aihara

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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Tel. +49 911 655-5225
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Mail service@de.tuv.com
Web www.tuv.com/safety

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SELVAS Healthcare, Inc.
Mr. J. K. Baek
155, Shinseong-ro, Yuseong-gu
DAEJEON 34109
REPUBLIC OF KOREA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date November 26, 2018

Application for : QMS
Certificate No. : SX 60134339 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Mr. Baek,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60134339 0001.

Kind regards

Certification body

Aihara

M.Sc. M. Aihara

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SELVAS Healthcare, Inc.
155, Shinseong-ro, Yuseong-gu
Daejeon 34109
Republic of Korea

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

Manufacture and Distribution of Non-Invasive Blood Pressure Monitors and Body Composition Analyzers

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:	2018-11-26
Certificate Registration No.:	SX 60134339 0001
An audit was performed. Report No.:	12022725 007
This Certificate is valid until:	2021-05-20

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date 2018-11-26

M.Sc. M. Aihara

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®

EC Certificate

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

Registration No.: DD 60125185 0001

Report No.: 12022725 005

Manufacturer:
SELVAS Healthcare, Inc.
155, Shinseong-ro, Yuseong-gu
Daejeon 34109
Republic of Korea

Products:
- Non-Invasive Blood Pressure Monitors
- Body Composition Analyzers

Expiry Date: 2020-11-25

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: 2017-12-22

Date: 2017-12-22

Notified Body

M.Sc. M. Aihara

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.

HERITAGE
MEDICAL

Więcej informacji na temat analizatora ACCUNIQ znajdą na naszej stronie:

urzadzenia-medyczne.com.pl

Zapraszamy również do kontaktu telefonicznego lub mailowego:

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