EC Declaration of Conformity

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

whose single Authorized Representative:
VITAKO Sp. z o.o.
ul. Stanislawa Zaryna 7c 02-593 Warszawa,
POLAND

We, the manufacturer, herewith declare that the products

Body Composition Analyzer
Model: ACCUNIQ BC380
UMDNS-Code: **17417**

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 60146555 0001
Expiry date: 26.05.2024

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, Sinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea
Factory: 155, Sinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea

Daejeon, 04, FEB 2020
Place, date

Jin-Kyu Baek /QMR
Legally binding signature, Function