Declaration of Conformity

In accordance with Medical Device Regulation (EU) 2017/745 of the European Parliament and of the council amended by Regulation (EU) 2020/561

Manufacturer is exclusively responsible for the declaration of conformity

MANUFACTURER:	**EUROPEAN REPRESENTATIVE:**
SELVAS Healthcare, Inc. Address: 155, Shinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea	Obelis s.a. Address: Bd. Général Wahis, 53, B-1030, Brussels, Belgium

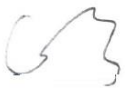
WE, SELVAS Healthcare, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDED BY REGULATION (EU) 2020/561; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
A STATEMENT THAT THE MANUFACTURER IS SOLE RESPONSOLE FOR THE EU DECLARATION OF CONFORMITY.

RELEVANT REGULATION: Medical Device Regulation (EU) 2017/745 of the European Parliament and of the council amended by Regulation (EU) 2020/561

PRODUCT NAME:	Body Composition Analyzer
MODEL NAME:	ACCUNIQ BC310 with column
INTENDED PURPOSE:	This device measures impedance by bioelectrical impedance analysis method and providers lots of information using measured impedance and inputted personal data (height, age, gender, weight). It shows body composition of MBF, LBM, SLM, SMM, TBW, protein mass, mineral mass, etc. and information regarding BMI, PBF, BMR, abdominal analysis, Target to control, segmental analysis, Body composition change, etc. Intended application location is professional healthcare facility environments, not home healthcare environment.
CONFORMITY ASSESSMENT PROCEDURE:	TD (Annex IX Chapter II) + QMS (annex IX Chapter I, III) + DoC (Annex IV) and CE Marking (Annex V)
CLASSIFICATION:	Class IIa: Rule 10 according to EU MDR ANNEX VIII
EMDN:	Z12099001
Basic UDI-DI:	8805116000119YC
APPLIED STANDARD:	EN ISO 13485:2016, ISO 14971:2007, EN 60601-1:2006, EN 60601-1-2:20007, EN 60601-1-6:2010, EN 62304:2006, EN 62366:2008, EN ISO 15223-1:2016, EN 1041:2008, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010
NOTIFIED BODY:	CE 0197 TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg, Germany
MDD Certification No.:	DD 60146555 0001

PLACE: 155, Shinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea

DATE OF ISSUE: 02, May, 2022

SIGNATURE: 

Jin-Kyu Baek / QMR