Manufacturer: **smartQare B.V.**
Kapteynstraat 1
2201 BB Noordwijk
The Netherlands

Declares under our sole responsibility that the product:

(according to the MDR Annex-IV)

Product name	viQtor
Product type	Remote patient monitoring solution
Intended Purpose	smartQare's solution 'viQtor' is intended to monitor adult users through: (I) periodic transfer (per 5 minutes) of health data and (II) events and help requests to a professional healthcare organization and/or medical service center and its healthcare professionals. viQtor measures blood oxygen saturation (SpO2), pulse rate and skin temperature of adult users in the hospital, nursing/care facilities and the home environment, and enables remote trend monitoring by periodic transfer of the data to a professional healthcare organization, in order to be reviewed by healthcare professionals. In addition, viQtor monitors the activity of the user, and detects a possible fall. In case of a possible fall, the device sends an attention request to the professional healthcare organization and/or medical service center. The user also has the possibility to send an attention request to the professional healthcare organization and/or medical service center by pressing the help button
Product Parts	Device (incl. charger) Mobile App Web Portal Backend
Product Accessories	Armband
Basic UDI-DI	Device: 087202995724 (MDR Annex-VI)
Single Registration Number (SRN)	NL-MF-000003491

To which this Declaration relates is in conformity with the provisions of Council Directive: EU 2017/745 (Medical Devices Regulation).

The Manufacturer is certified by the Notified Body listed below to ISO-13485:2016 and Annex IX of the Medical Device Regulation EU 2017/745. Copies of the smartQare Quality Management System certificates are available upon request.

Notified Body:	**KIWA DARE B.V.** **Vijzelmolenlaan 7** **3447 GX Woerden** **The Netherlands**
Identification nr.	**1912**
ISO-13485:2016 Certificate nr.	: 22M00183CRT01
CE Certificate nr.	: 22M00055CRT01

Supplementary Information:
The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation and are fully compliant with the directives and standards listed on next pages. Additionally, the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation:

This certificate is valid until: : **24 Aug. 2027** (note: validity date max.5 years from issue date)

Date: 03 Oct. 2022

Cecile Goldman
CEO
smartQare B.V.

Date: 03 Oct. 2022

Souraya Verhaegen
QA/RA Manager / PRfRC
smartQare B.V.

Place of Issue: **Noordwijk**

The object of the Declaration described above is in conformity with the following regulations, standards, and directives:

EU Regulation	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 on medical devices (EU MDR)**
Device Risk Classification	Class IIa, according to Annex VIII and rules 1, 10, 11 and 13
Standards	The products listed on this Declaration of Conformity have been assessed and/or tested in a typical configuration as described in the Manufacturer's accompanying documentation in accordance with the product standards listed below. Refer to Attachment A
EU Directive	**Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restrictions of the use of certain hazardous substances in electrical and electronic equipment, amended up to and inclusive of Directive (EU) 2017/2102 (RoHS)**
EU Directive	**Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) Text with EEA relevance. Waste from Electrical and Electronic Equipment**
EU Directive	**Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC**
EU Directive	**Radio Equipment Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance**

Attachment A

Applied Standards and Guidance for viQtor:

Standard Number	Standard Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 15223:2016	Medical Devices – Symbols to be used with medial device labels, labelling and information to be supplier
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medial device labels, labelling and information to be supplier – Part1: General Requirements.
EN ISO 10993:2010	Biological Evaluation of Medical Devices.
NEN-EN-ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
NEN-EN-ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
NEN-EN-ISO 10993-10:2010	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
NEN-EN-ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
EN ISO 20417:2021	Medical Devices – Information to be supplied by the manufacturer
IEC 60601-1:2005/AMD1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz-300 GHz)
IEC 80601-2-61:2017	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 62304:2015	Medical device software – Software life cycle processes
NEN-EN 50566:2017	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body.
MEDDEV 2.7/1 Rev. 4	Guidelines on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC
ETSI EN 301 489-1 V2.2.3	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard for ElectroMagnetic Compatibility
ETSI EN 301 489-3 V2.2.1	Specific conditions for Short Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard for ElectroMagnetic Compatibility
ETSI EN 301 489-19 V2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 19: Specific conditions for Receive Only Mobile Earth Stations (ROMES) operating in the 1,5 GHz band providing data communications and GNSS receivers operating in the RNSS band (ROGNSS) providing positioning, navigation, and timing data; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
ETSI EN 301 489-52 V3.2.4	EMC - Specific conditions for Cellular Communication User Equipment (UE) radio and ancillary equipment; Harmonised Standard for ElectroMagnetic Compatibility

ETSI EN 301 908-1 V13.1.1	IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 1: Introduction and common requirements
ETSI EN 301 908-13 V13.1.1	IMT cellular networks; Harmonised Standard for access to radio spectrum; Part 13: Evolved Universal Terrestrial Radio Access (E-UTRA) User Equipment (UE)
ETSI EN 303 417 V1.1.1	Wireless power transmission systems, using technologies other than radio frequency beam in the 19 - 21 kHz, 59 - 61 kHz, 79 - 90 kHz, 100 - 300 kHz, 6 765 - 6 795 kHz ranges; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 303 413 V1.1.1	Satellite Earth Stations and Systems (SES); Global Navigation Satellite System (GNSS) receivers; Radio equipment operating in the 1 164 MHz to 1 300 MHz and 1 559 MHz to 1 610 MHz frequency bands; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU