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 Code	viQtor 2
Product type	Remote patient monitoring solution
Intended Purpose	The intended use of the viQtor solution is to periodically transfer health data and events to a professional healthcare organization for assessment by healthcare professionals. It measures oxygen saturation (SpO2), pulse rate (PR), respiratory rate (RR) of adult (18 years and older) users in hospitals, nursing homes, and home settings, allowing remote monitoring and assessment of trends by healthcare professionals. Additionally, viQtor monitors skin temperature, user activity and detects potential falls. In case of a possible fall, the device sends a request for attention to the professional healthcare organization. The user also has the option to send a request for assistance to the professional healthcare organization a by pressing the assistance request button.
Product Parts	Device (incl. charger) Mobile App Platform
Product Accessories	viQtor Armband model 1: 872029957245496 Class I (green armband) viQtor Armband model 2: 8720299572478 Class I (silicon armband)
Basic UDI-DI	Device: 087202995724098Z (MDR Annex-VI) Platform : 87202995724238T (MDR Annex-VI) Mobile App : 87202995724308Q (MDR Annex-VI)
Single Registration Number (SRN)	NL-MF-000003491

Complies with the requirements set in: MDR (EU) 2017/745.

DS SV DS WJP

To which this Declaration relates is in conformity with the provisions of Council Regulation: (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 regulation, directives and common specifications (when applicable) 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: 01 May 2024

DocuSigned by:
W.J.P. van Kuijen
483146CF32BA49A...

Walter van Kuijen
CEO
smartQare B.V.

Date: 01 May 2024

DocuSigned by:
S. Verhaegen
31020D7C4956412...

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, directives and or common specifications (when applicable):

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**
Conformity assessment route chosen	**Annex IX of the MDR (EU) 2017/745.**
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, Authorization 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 harmonization 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**
Common Specifications (CS)	**N.A.**

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