



TO WHOM IT MAY CONCERN

ATTESTATION

Undersigned confirms that CURAVISTA BV established at Oeverkruid 13, 4941 VV Raamsdonksveer, The Netherlands, EUDAMED: NL-MF-000028855, has signed a certification agreement with SGS Belgium NV Business Assurance for ISO13485:2016 and MDR Annex 9 QMS. Such with reference to Regulation 2023/607/EU, article 3b and 3c – sub (e).

The initial audit will be scheduled and performed by auditor Hans van Daal.

The certificate for ISO13485:2016 and 2017/745/EU (MDR) Annex 9 QMS will be presented after an audit with positive result and as soon as all documents are approved by the Certification Council of SGS.

This statement is valid for the following scopes:

ISO 13485 (BELAC / UKAS):

Design, development, manufacture, distribution, installation and service of monitoring software for people with chronic diseases and/or medical conditions for which a doctor has been consulted.

2017/745/EU (MDR) Annex 9 QMS:

Gezondheidsmeter is a monitoring software intended to be used for people with chronic diseases to improve decision making in the diagnosis or therapeutic process for which a doctor has been consulted. (Class IIa, MDA 0315, MDS 1009)

Basic UDI-DI: 8720892GZM23.01Y8

This statement is valid from 12 July 2024 until 24 April 2025 (such based on 2023/607/EU, article 3b and 3c – sub (e))

Lieven de Smet
Operations Manager
SGS Belgium NV - Business Assurance