

Certificate of Approval

This is to certify that the Management System of:

Quin B.V.

Stadhouderskade 55, 1072 AB Amsterdam, The Netherlands

has been approved by LRQA to the following standards:

ISO 13485:2016, ISO 9001:2015

Approval number(s): ISO 13485 – 00053243, ISO 9001 – 0081397

The scope of this approval is applicable to:

ISO 9001:2015

Design, development, production, and maintenance of digital health software, including Software as a Medical Device (SaMD), and provision of related services. Distribution of third-party SaMD in accordance with applicable regulatory requirements.

ISO 13485:2016

Design, development, production, and maintenance of Software as a Medical Device (SaMD) and provision of related services for application in the digital care pathway for patients with disorders of gut-brain interaction. Distribution of third-party SaMD in the Netherlands in accordance with EU MDR 2017/745 Article 14 distributor obligations for support of general practitioners.

Marta Escudero

Regional Director, Europe

Issued by: LRQA Limited

