Declaration of Software Verification
FLUENTCONTROL 3.4

FluentControl 3.4 software has been designed, verified and validated according to the Tecan Product Development Process. Software Verification is performed to ensure that the Design Output meets the Design Input Requirements. Design Validation is performed to ensure that the product meets the User Needs and Intended Use. Typical process documents of the Product Development Process include but are not limited to Verification Reports, Design Validation Reports, Risk Management, as well as Manuals and Help files. Master Media for software distribution is scanned to be malware-free.

Tecan performs IQ and OQ on instrument installation. PQ is the customer's responsibility and is specific to their Fluent's application.

Our commitment to continuous improvement is certified by our registration to ISO 9001:2015 and ISO 13485:2016 quality system standards. Tecan's software development complies with IEC 62304 – medical device software – software life cycle processes. To view our certificates online, please scan the QR code below.

Christian Feuerstacke	Product Manager Software, T-CH DocuSigned by: Signer Name: Christian Feuerstacke Signing Reason: I am the author of this document Signing Time: 2023-06-02 | 10:15:15 AM CEST 537FE4EEFC0840A99EE474D1E095F160
Asmaa Edres-Lohaus	Software Project Manager, T-SCC DocuSigned by: Asmaa Edres-Lohaus Signer Name: Asmaa Edres-Lohaus Signing Reason: I have reviewed this document Signing Time: 2023-06-09 | 8:50:19 AM CEST A9ED6834BB2A4728B05D5BD3DEE21266
Johann Israel	Director QA/RA, T-CH DocuSigned by: Signer Name: Johann Israel Signing Reason: I approve this document Signing Time: 2023-06-09 | 11:15:49 AM CEST 1B7C02D2F58F42FD89226D4DA71CF4B3