Declaration of Software Verification
FLUENTCONTROL 3.7

FluentControl 3.7 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.

Rachel Begheyn — Product Manager Software, T-CH

Signed by:
R. F. Begh
Signer Name: Rachel Begheyn
Signing Reason: I am the author of this document
Signing Time: 2024-12-10 | 5:21:03 PM CET
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Asmaa Edres-Lohaus — Software Project Manager, T-SCC

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Johann Israel — Director QA DACH, T-CH

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