# Confirmation of Compliance

of Multiwave 5001/3001/5000 software 3.0
with the U.S. Food and Drug Administration regulation Part 11 of Title 21 of the Code of Federal Regulations

## Multiwave 5001/3001/5000

## 1   Audit Target

In December 2024, Anton Paar GmbH has audited the software Multiwave 5001/3001/5000 version 3.0, used for the operation of Multiwave 5001/3001/5000 in respect of Part 11 of Title 21 of the Code of Federal Regulations.

## 2   Certification of compliance

Anton Paar GmbH hereby confirms that the above-mentioned software contains all **technical controls** for compliance with Part 11 of Title 21 of the Code of Federal Regulations. This regulation requires computerized systems to include technical controls to assure that

- electronic records maintain security and integrity and are as verifiable as paper records; and

- electronic signatures meet standards that allow them to have the same legal bearing as traditional handwritten signatures.

**Overall compliance** with Part 11 of Title 21 of the Code of Federal Regulations can only be met together with the operational environment. Therefore, it is the responsibility of the operator to correctly and consistently implement the procedural and administrative controls (such as technical environment, data management, notifications, administration, training, standard operating procedures) and to use the product with the correct technical controls.

Given that the operator responsibilities concerning the procedural and administrative controls are met, the Multiwave 5001/3001/5000 software is compliant with Part 11 of Title 21 of the Code of Federal Regulations and is well-suited for the implementation in controlling the instrument.

## 3   Basis for certification

The above certification is based on the following audit results:

I.   The Multiwave 5001/3001/5000 software version 3.0 contains the technical controls for limitation of and authorization for the system by user verification through the usage of passwords, therefore assuring electronic record integrity. The User identification code and password are required during electronic signature executions.

II.  All technical controls providing limitation and authorization require the operator to use the correct technical controls and to correctly and consistently implement the corresponding procedural and administrative controls such as technical environment, data management, notifications, administration, training, Standard Operating Procedures. The software can only provide a technical base for limitation and authorization only effective if and to the extent such controls are implemented.

III. Permission to access or modify tasks can be permitted by an administrator and users are individually identified to track who has created, modified or signed an electronic record so

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there is a clear link between an electronic signature and the data file including signer, date, time and meaning and non-repudiation is guaranteed. Any changes made after the electronic signature is executed can be detected.

IV.     Users are only allowed to create, edit and delete contents according to the security and/or permission level they have been granted via user role on a role-based security model.

V.      User actions and workflow events are recorded by a secure, computer-generated audit trail protecting the contents, identifying the details of the changes made and guaranteeing the possibility to reconstruct the content prior to changes. Workflows must be executed in the permitted sequence.

VI.     Unauthorized password use is reported and accounts are disabled upon multiple unsuccessful attempts to log in. The User Identification codes are unique – no two user accounts can have the same code – and therefore, the electronic signature is as well.

This is confirmed on behalf of Anton Paar GmbH by its authorized representative.

DocuSigned by:

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