

GAMP Certificate

Software: IONIC App
Version: 1.0



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Assessment date: 28-Sep-2026

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Assessment objective: Classification of *IONIC App 1.0* into the GAMP5 software categories.

Object description: The *IONIC App* is a software to control the IONIC Titrator (a compact titration system for volumetric titration – consisting of the touch-sensitive color monitor, the titration unit, and the magnetic stirrer) and runs on the IONIC Titrator hardware. It features creating methods, performing determinations (titrations and measurements), data acquisition, evaluation and archiving in a local database.

The software was developed by Metrohm AG in accordance with ISO 9001 requirements regarding design, manufacturing, and maintenance.

Categorization: *IONIC App* predominantly consists of “Standard Components” (GAMP5 software category 3), supplemented by “Configured Components” (GAMP5 software category 4).

Rationale:

The software configuration is limited to:

- Customization of user-specific business processes¹ by means of:
 - Assignment of process-specific user rights (i.e. user role) to individual users (i.e. user accounts)
 - Configuration of compliance-related settings, particularly for the use of electronic signatures and audit trails.

Such configurations have a reasonable impact on the way *IONIC App* is supporting the lab processes of the user.

- Creation of process-driving/controlling datasets:
Creation and modification of methods drive and control the actual lab workflows. But working with such data sets is part of the routine work and is supported by *IONIC App* based on built-in standard system functionality (i.e. those functions are not adapted to user-specific business processes²).

During system operation some or all of these process-driving/controlling datasets are adapted on a case-by-case basis to meet the respective analytic demand. This must be controlled by appropriate specification, testing and verification. Such measures must be implemented as part of the operational controls to maintain the validated state.

¹ see definition of Software Category 4: GAMP5 Second Edition, Appendix M4, Chapter 12.3.4

² see definition of Software Category 3: GAMP5 Second Edition, Appendix M4, Chapter 12.3.3



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