

ERES Certificate

Software: IONIC App
Version: 1.0



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Assessment date:	28-Sep-2026 ¹								
Auditor:	Sieghard Wagner, mech. Engineer (grad.), Chemengineering Germany GmbH								
Assessment objective:	Compliance check against the ERES ² requirements of FDA 21 CFR Part 11 and EudraLex, Volume 4, Annex 11 ³ for <i>IONIC App 1.0</i> .								
Object description:	The <i>IONIC App</i> 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.								
Approach:	The functions and properties of the above software system are audited against the ERES requirements of 21 CFR Part 11 and EU GMP Annex 11 with its current interpretations. The assessment was guided by a requirements checklist, which is based on the respective 21 CFR Part 11 and Annex 11 paragraphs.								
Assessment results:	▪ Operator responsibility ERES compliance requires an appropriate operational environment. It is the operator's responsibility to provide a compliant environment regarding the following points: ▫ Technical environment, data management ▫ Training ▫ Administration ▫ Standard Operating Procedures (SOP). ▪ Summary The software is compliant with the following ERES requirements: <table border="0"> <tr> <td>21 CFR Part 11:</td><td>11.10 (b), (d), (f), (g); 11.30, 11.50, 11.70; 11.300 (a)</td></tr> <tr> <td>EU GMP Annex 11:</td><td>Paragraphs: 5, 6, 8, 9, 12, 14b, 14c</td></tr> </table> The software is compliant with the following ERES requirements with support of the operator: <table border="0"> <tr> <td>21 CFR Part 11:</td><td>11.10 (a), (c), (e), (h), (i), (j), (k); 11.100 (a), (b); 11.200 (a); 11.300 (b), (c), (d)</td></tr> <tr> <td>EU GMP Annex 11:</td><td>Paragraphs: Principles, 1 to 4, 6, 7, 9, 10, 14a, 17</td></tr> </table> The software supports electronic signature.	21 CFR Part 11:	11.10 (b), (d), (f), (g); 11.30, 11.50, 11.70; 11.300 (a)	EU GMP Annex 11:	Paragraphs: 5, 6, 8, 9, 12, 14b, 14c	21 CFR Part 11:	11.10 (a), (c), (e), (h), (i), (j), (k); 11.100 (a), (b); 11.200 (a); 11.300 (b), (c), (d)	EU GMP Annex 11:	Paragraphs: Principles, 1 to 4, 6, 7, 9, 10, 14a, 17
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EU GMP Annex 11:	Paragraphs: Principles, 1 to 4, 6, 7, 9, 10, 14a, 17								

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¹ This ERES certificate is based on an on-site audit performed 20-August-2026. Subject of this audit was the software version 1.0 with all compliance features enabled.

² Electronic Records, Electronic Signatures

³ see EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines