



EU Annex 11 Compliance Matrix for the Compliance Version of Spectrum™ Plus

Aperio's Compliance Version of Spectrum Plus is designed to facilitate your compliance with EU's Annex 11¹. This table shows which features of Spectrum Plus comply with topics in Annex 11, and shows how you can develop a solution for your company that is compliant with Annex 11.

Topic	Annex 11 Section	Compliance Strategy
Risk Management	1	Aperio has completed a comprehensive risk analysis for the Spectrum Plus software and ScanScope® instrumentation. The risk analysis is founded in contemporary concepts, such as ISO 14971:2007.
Personnel and Training	2, 7.1	Aperio maintains a training program that documents employees' training on technical and regulatory topics. Aperio can assist you with preparation of a training plan so your staff understands how to use the Spectrum Plus and ScanScope products, as well as the implications of Annex 11.
Validation	3.1 – 3.7, 7.1	<ul style="list-style-type: none"> Aperio has validated the ScanScope instrumentation and Spectrum Plus software. Aperio provides a suite of validation protocols that comprehensively qualify the installation, operation, and performance of ScanScope and Spectrum Plus at your company. These protocols include calibration of: <ul style="list-style-type: none"> Mechanisms that ensure data integrity and security Transaction control Data backup and recovery mechanisms Performance of the system under load Data archival Your company should maintain policies for computerized system validation, change control and configuration management. Aperio can help you prepare these.
System Inventory	4.1	All system components, including computer hardware and ScanScope instrumentation, are inventoried at your site in Aperio's validation protocol suite.
System Specifications	4.2	Aperio maintains a specification set for Spectrum Plus and ScanScope, which is based on contemporary life-cycle concepts (e.g., GAMP 4 and 5).
Software QA and QMS	5	Aperio employs an independent quality unit, which directs the Quality Management System and oversees software Quality Assurance (QA).
Access Control and Logical Security	6.1, 8.1, 8.2, 8.3, 8.5, 14.1	<p>Proper user credentials are required to access Spectrum Plus.</p> <ul style="list-style-type: none"> Spectrum Plus features a comprehensive set of permissions and roles that administrators can grant to or restrict from users. Through requirement of proper user credentials and enforcement of role and permission restrictions, Spectrum Plus data is secured against willful and accidental damage. Aperio encourages you to develop policies for physical security to complement Spectrum's logical security capabilities. Spectrum Plus detects attempts at unauthorized access and can notify appropriate personnel of such attempts. Aperio encourages you to develop an Information Security Management System to cover user responsibilities, granting of user privileges, and logical security. Aperio can assist you with developing a policy.

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Audit Trails	6.1, 8.4, 10.1, 13.1	<ul style="list-style-type: none"> Spectrum Plus audit trails are secure, immutable by ordinary means, and time-stamped. They record the date and time of all entries and actions that create, modify, or delete data, along with the name of the person who performed the action. Audit trails can be presented in a human-readable form. Printouts of records indicate data changes.
Accuracy Checks	9	This topic is not applicable to Spectrum Plus. It is the responsibility of the user to ensure that data entered to Spectrum Plus is accurate.
Electronic Signature	11.1, 11.2	<ul style="list-style-type: none"> To electronically sign a document, Spectrum Plus requires users to enter their unique user ID, their password, and a meaning of the signature. Signatures are irrevocably linked to source records in the Spectrum Plus database. Spectrum Plus automatically captures the date and time that a signature was executed. While Spectrum Plus is capable of rendering fully compliant electronic signatures, it is your company's responsibility to declare that electronic signatures are the legally binding equivalent to handwritten signatures.
Change Control & Configuration Management	12.1	<ul style="list-style-type: none"> Aperio maintains change control and configuration management procedures as part of its Spectrum Plus software life cycle program Aperio encourages you to maintain change control and configuration management procedures at your site. Aperio can help you prepare these procedures.
Data Backup, Restore, Archival, and Business Continuity	15, 16	<ul style="list-style-type: none"> Aperio's user manuals provide you with procedure for backing up and restoring electronic records. Aperio validates backup and restore features at your site as part of our comprehensive validation protocol suite. It is your responsibility to develop procedures for record retention, archival, backup, restore, and business continuity. Aperio can assist you with developing these procedures.
Incident Management	17	<ul style="list-style-type: none"> Aperio records software issues that customers report. Aperio tracks and analyses these issues, and implements suitable corrective actions, such as customer alerts and software updates. It is your responsibility to develop a procedure for incident management at your site. Aperio can assist you with developing this.
Suppliers	18	All Aperio installations, including configuration and validation services, are accompanied with a formal agreement that delineates Aperio's responsibilities.
Batch Release	19	This topic is not applicable to Spectrum Plus, as Spectrum Plus is not designed for batch release operations.

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1 Annex 11, "Computerised Systems," 4/8/2008 draft, in *The Rules Governing Medicinal Products in the European Union*, Volume 4: "EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use," EudraLex.

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