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21 CFR Part 11 Compliance Module (X2)

WX-001-0187

More information on the website
mirror.radwag.com/en/info,w1,U5R



The drawings, photos and graphics used are for illustrative purposes only.

Overview

The 21 CFR Part 11 Compliance Module is a solution especially useful for those users who are obliged to conform to provisions of 21 CFR Part 11 and EU GMP Part 4, Annex 11 regulations. These two documents determine the rules for using electronic records and signatures. Data protection is guaranteed by: advanced password settings, control of logging correctness, various permission levels, data management access, backup, electronic signature, time-defined automatic logout, modification record to Audit Trail file.
The module includes "Audit Trail". Audit Trail is a kind of a log where all modifications of balance settings, changes in database records and user activity are recorded. Audit Trail, for example, keeps record of previous and new modifications in databases and informs by whom and when they were introduced. This log allows the administrator to track and find out who logged in, when, who signed a document or who used invalid password. The Audit Trail Reader freeware allows users, upon connection with a balance, to display Audit Trail log and manage it by generating reports of various formats: pdf, xls, csv, html.

Compatible with (Additional Fee)

MA X7.IC.A Moisture Analyzer
AS X7 Analytical Balance
MA X7.A Moisture Analyzer
PS X7 Precision Balance