# 21 CFR Part 11 Compliance Module (4Y, 5Y, CY10)

WX-001-0133

More information on the website
mirror.radwag.com/en/info,w1,U1I




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)

XA 5Y.M.A.P Microbalance for pipettes calibration

XA 5Y.F Analytical Balance for Filters

MYA 5Y.P Microbalance for pipettes calibration
AK-5/100.STENT Automatic Balance for Stents
UMA 5Y.F Automatic Weighing System
MA 5Y Moisture Analyzer
5Y.PM Precision Balance
MYA 5Y.F Microbalance for Filters
XA 5Y.M.A Microbalance
CY10 Scales for PGC
PUE CY10 Weighing Terminal
CY10 Multifunctional Scale
XA 5Y.A Analytical Balance
WAY 5Y.KO Manual Mass Comparator
Robotic Mass Comparators
UYA 5Y Ultra-Microbalance
MA 5Y.IC Moisture Analyzer
AS 5Y Analytical Balance
AK-4 Automatic Mass Comparator
PS 5Y Precision Balance
PS 5Y Balances for PGC
AKM-2 Automatic Mass Comparator
CY10 Precision Balance
UMA Automatic Mass Comparator
APP 5Y.KO Manual Mass Comparator
Density Measurement
MYA 5Y Microbalance
XA 5Y Analytical Balance
Manual susceptometers - Magnetization
5Y.PM.KB Manual Mass Comparator
HRP 5Y.KO Mass Comparator
Automatic Vacuum Mass Comparators
PMV 5Y Moisture Analyzer
Automatic susceptometers - Magnetization
XA 5Y.KO Manual Mass Comparator
HRP 5Y.KB Mass Comparator
XA 5Y.M Microbalance
RMC F Robotic Weighing System
RB F Robotic Weighing System
UYA 5Y.KO Manual Mass Comparator
UYA 5Y.F Ultra-Microbalance for Filters
XA 5Y.M.A.S Microbalance for stents weighing
AK-6 5Y.F Automatic Weighing System