



## Modulo di conformità CFR 21 parte 11 (X2)



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

### Caratteristiche generali

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.

### Compatibile con

Termobilancia MA X7.IC.A  
Termobilance MA X2.IC.A  
AS X7 Bilancia analitica  
Bilance di precisione PS X2  
Bilance analitiche AS X2 PLUS

Bilance PS X7 per controllo CPC  
Bilance PS X2 per controllo CPC  
Termobilance MA X2.A  
Termobilancia MA X7.A  
Bilancia di precisione PS X7