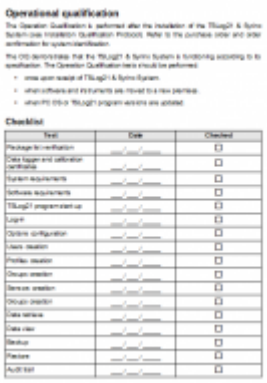
Protocolli IQ/OQ/PQ per TSLog 21

I documenti relativi ai protocolli di qualifica per installazione, funzionamento e prestazioni sono disponibili per i sistemi Tecnosoft compatibili con la normativa FDA 21 CFR Part 11, Annex 11 e GAMP.

I documenti sono personalizzati per ogni cliente e possono essere compilati direttamente dall'utente. In alternativa è possibile chiedere a Tecnosoft di eseguire la qualifica.



Operational qualification

The Operation Qualification is performed after the installation of the TSLog21 & Sylmo system (see Installation Qualification Protocol). Refer to the purchase order and order confirmation for system identification.

The OQ demonstrates that the TSLog21 & Sylmo System is functioning according to its specification. The Operation Qualification tests should be performed:

- once upon receipt of TSLog21 & Sylmo System;
- when software and instruments are moved to a new premises;
- when PQ OQ-2 TSLog21 program versions are updated.

Checklist

Test	Date	Checked
Package for verification	__/__/____	☐
Data logger and calibration certificates	__/__/____	☐
System requirements	__/__/____	☐
Software requirements	__/__/____	☐
TSLog21 program start up	__/__/____	☐
Login	__/__/____	☐
Options configuration	__/__/____	☐
Users creation	__/__/____	☐
Profiles creation	__/__/____	☐
Groups creation	__/__/____	☐
Sensors creation	__/__/____	☐
Groups creation	__/__/____	☐
Data retrieve	__/__/____	☐
Data view	__/__/____	☐
Backup	__/__/____	☐
Restore	__/__/____	☐
Audit trail	__/__/____	☐

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