

# 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 & Spine System and the Installation Qualification Protocol. Refer to the software user and user administrator for system distribution.

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

- when new version of TSLog21 & Spine System
- when software and its functions are moved to a new platform
- when the OQ or PQ program version are updated

#### Checklist

Test	Case	Checked
Package identification	OK	<input type="checkbox"/>
Data system and calibration	OK	<input type="checkbox"/>
Installation	OK	<input type="checkbox"/>
System requirements	OK	<input type="checkbox"/>
Software requirements	OK	<input type="checkbox"/>
TSLog21 programming up	OK	<input type="checkbox"/>
Setup	OK	<input type="checkbox"/>
System configuration	OK	<input type="checkbox"/>
Access operation	OK	<input type="checkbox"/>
Profile operation	OK	<input type="checkbox"/>
Display operation	OK	<input type="checkbox"/>
Device operation	OK	<input type="checkbox"/>
Output operation	OK	<input type="checkbox"/>
Data retrieval	OK	<input type="checkbox"/>
Data view	OK	<input type="checkbox"/>
Device	OK	<input type="checkbox"/>
Printer	OK	<input type="checkbox"/>
Audit trail	OK	<input type="checkbox"/>

