

AZ 的 USB 温湿度记录器是否符合 FDA 21 CFR Part 11?

回复:

请注意, FDA 21 CFR Part 11 的规定是针对软件的。

由于 AZ 的 USB 数据记录器不需要用户安装任何软件, 所以它不适用, 或者说它不符合 FDA 21 CFR Part 11 规定。

Question

Is AZ's USB Datalogger compliant with FDA 21 CFR Part 11?

Reply:

Please note that the regulation of FDA 21 CFR Part 11 is for the software.

Due to AZ's USB datalogger don't required user to install any software, please note that it's not applicable, or you can say it's not complying with the FDA 21 CFR Part 11 regulation.