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Wednesday, December 18, 2013

Statement on Calibration for Welch Allyn PC Based ECG System

There is no Calibration Certificate for the electrocardiogram functionality of the CPWS PC Based ECG System because calibration on the system is not required.

The CPWS PC Based ECG system Pro Recorder is manufactured in accordance with its Device Master Record and must pass all applicable testing including final functional testing. Evidence of conformity is contained in the Device History Record for each device and can be provided upon request in a Certificate of Analysis.

I make these statements believing the same to be true and accurate.

Respectfully submitted,

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Date