August 10, 2020

Re: Quest Required Certifications

Dear QMED Customer,

Quest is a cellular IoT asset tag that provides daily information regarding the location of your instrument sets, or asset. Based on the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act, the Quest product is not a medical device.

Since Quest is not a medical device, Quest is out of scope for IEC 60601, Medical Electrical Equipment. Since Quest is a cellular, or mobile, IoT device it must have Regulatory Certification, Telecom Industry Certification and Operator Certification.

Regulatory Certifications are mandatory for the product to be sold in a specific market. The Regulatory Certifications demonstrate compliance with regulations to ensure safety and to ensure device RF emissions so not interfere with other wireless equipment and includes RF Transmitter and receiver tests, electromagnetic compatibility, and electrical safety. Regulatory Certification for the US is Federal Communications Commission (FCC) part 18, Industry Canada (IC) for Canada and European Telecommunications Standards Institute (ETSI) for Europe.

Telecom Industry Certification checks the functionality of the product and conformance to specific industry standards. PTCRB, PCS Type Certification Review Board, is the mandatory Telecom Industry Certification for devices that use the networks of operators and cover testing to 3GPP standards, SIM/eSIM functionality and antenna performance.

Operator Specific Certification is an additional layer above the Telecom Industry Certification to test operability to a specific network. This testing is typically required for a device to be used on a specific network or across a group of network operators. If a device roams on multiple networks, the Operator Specific Certification is only required on the network that provides the cellular subscription.

Quest has received FCC Certification, FCCID is XMR201910BG95M3, Canadian Certification, IC 10224A-2019BG95M3, PTCRB and AT&T Operator Certification.

Sincerely,

Shelby Kornbluth

VP Product Development

QMED Innovations