Retlif Receives ASCA Pilot Program Accreditation from FDA

Three Retlif laboratories expand Scope of Accreditation for Medical Devices Testing

RONKONKOMA, NEW YORK, USA, July 26, 2021 /EINPresswire.com/ -- A globally recognized, independent EMC/EMI and environmental testing organization, Retlif Testing Laboratories has achieved a significant milestone with FDA ASCA pilot program accreditation.

Typical Medical Device ASCA Applications Retlif testing

One of the first independent EMC (Electromagnetic Compatibility) laboratories to gain accreditation in the USA, Retlif supports conformity assessment schemes with test data from ISO/IEC 17025-accredited labs. The US Food and Drug Administration (FDA) has recently embraced accreditation through a pilot program, the Accreditation Scheme for Conformity Assessment (ASCA).

ASCA incorporates international conformity assessment standards and practices with the goal of increasing confidence in medical device testing among FDA reviewers and medical device manufacturers. Anticipation is that this will decrease requests for additional information relating to testing methodologies when pre-market submissions include a declaration of conformity to an FDA-recognized consensus standard within the FDA ASCA Pilot Program.

Scopes of Accreditation include basic EMC requirements contained within IEC 60601-1-2, Edition

4.0, 2014 including requirements for medical electrical equipment and systems used in home health care and emergency medical services environments. According to Retlif President Walter Poggi, "product testing applications are extensive. They range from electrocardiographs and endoscopic equipment to ultrasonic diagnostic and monitoring equipment, to x-ray equipment for computed tomography. Dental intra-oral x-ray equipment are also included. The Pilot program is intended to increase consistency and predictability in the FDA's approach to assessing conformance with FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot in medical device premarket reviews."


Walter Poggi President of Retlif Testing Laboratories

Medical equipment manufacturers can readily access this alternative path for FDA acceptance of EMC test reports from Retlif. All three Retlif EMI/EMC facilities (Harleysville PA, Goffstown NH and Ronkonkoma NY) have achieved FDA ASCA Pilot Program accreditation.

For more information contact ASCA@Retlif.com.

About Retlif Testing Laboratories:

Founded in 1978 and headquartered in Ronkonkoma, New York, USA, Retlif Testing Laboratories is one of the USA's highest profile independent testing laboratories. Retlif provides complete EMC/EMI and Environmental Simulation Testing and engineering services for medical, aerospace and aviation, avionics, rail and transit, maritime, military, defense, and homeland security products. Retlif's test data is recognized worldwide. The organization is strategically focused on test results with a mission to provide tangible customer value through testing and engineering services.

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