

Compliance Solutions Update

July 2017

Cybersecurity for Network Connected Medical Devices

1 in 5 people will be the victim of a cybercrime and 90% of these incidents are due to defects in software.

The FDA has published several documents that outline their guidance on actions that manufacturers should take with medical devices that contain software and can be connected to IT networks through wired or wireless connections such as Wi Fi, Bluetooth, and even Cat 5 cable.

Included in these guidance documents is information which the FDA is expecting to be included in new 510(k) submissions of medical devices with software and network connections.



The UL 2900 series consists of several documents under the general title 'Standard for Software Cybersecurity for Network-Connectable Devices', and includes particular requirements for Healthcare Systems.

For more information on UL's cybersecurity services, contact Ken Wilson, Ken.Wilson@ul.com.

UL Prospector® - The Source for Technical Information



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For information on Prospector, contact Paul Deverall, Paul.Deverall@ul.com.

UL Acquires EMERGO

UL's recent acquisition of EMERGO marks a significant expansion of UL's regulatory services footprint in the medical device industry.



EMERGO provides regulatory value-added services and market access services to medical device manufacturers worldwide. We are pleased to welcome our new EMERGO colleagues, including local representation and services in Australia.

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UL Expands within the Construction Market

UL recently expanded its service offerings further into the Building Envelope and Building Sciences market with the acquisition of CLEB, a leading service provider in this industry. CLEB, a Montreal-based company, provides a wide range of building science services, including building envelope testing services, building forensic services, and field testing and building system commissioning services for architects, building owners, manufacturers and others in building construction.

This acquisition strengthens UL's expertise in the field of building science services and building envelope testing, and certification services, and offers manufacturing clients greater access to global markets.

For more information on UL's building science capabilities, contact Thomas Jones, Thomas.Jones@ul.com.

Fidget Spinners... safety concerns with this latest craze

Fidget Spinner toys are the new craze that has consumers searching the market, manufacturers struggling to keep up with demand, and expanding their supplier base to source ball-bearing components that give life to the endless spinning action.

As an item marketed to children for play, they are regarded as a "toy" and must comply with the applicable toy safety standards. Because of the small design and corresponding parts, these spinners can pose a choking hazard to children. There is also a huge variation in quality.



Spinners made from inferior material have broken when dropped releasing small parts and creating sharp pieces. New generation spinners have evolved to include design features with batteries and LEDs. Batteries are a known safety hazard if accidentally ingested and hence the robustness of the design, manufacturing processes and quality controls are critical.

UL's team of quality assurance experts is uniquely positioned to support the toy manufacturing industry's drive to bring safer products to the world market. UL can provide toy safety evaluation, and also offers a Toy Safety Certification Mark to help consumers identify product of the highest quality and safety.

ESV reviewing Gas Safety Regulation

ESV is leading the review of new Gas Safety Regulations to replace those due to expire in December 2018. They are seeking comments, concerns or queries over the way gas safety cases and gas installations in Victoria are regulated., via inforegulations@energysafe.vic.gov.au before 5pm Friday 28th July 2017.