

Compliance Solutions Update

February 2017



Preparing for EU Medical Device Regulation

New EU Medical Device Regulations are set to introduce major changes that medical device manufacturers will need to incorporate into their product design, clinical evidence and post-market activities. Although there is expected to be a transition period of 3-5 years, the regulation is such that all products will need to comply, whether or not they are previously approved.

It is of critical importance for those selling medical devices in the EU to understand the extent of the changes and the potential impact. *Linda Chatwin, RACJD* is a UL Senior Regulatory Consultant and has studied the new Regulations and summarized these changes in an article which can be accessed online with the link below.

<http://www.goo.gl/6zLjBt>

Pending Standard Change - Rating of Kitchen Machines

For many years, the marked rating on kitchen machines has been a reflection of perceived marketing advantage rather than actual power consumption during representative normal use. This will change with the adoption of an update to IEC 60335-2-14 which is soon to be considered for adoption into the AS/NZS equivalent standard.

When kitchen machines are subject to temperature rise testing, the current standard allows testing to be conducted using recipes from the Instruction Booklet instead of loading the appliance according to the marked power input. The latest edition of IEC 60335-2-14 requires appliances to be subject to an additional temperature test whilst loaded (by application of a constant torque) to the rated power input. This additional test is not applied where the power input during tests conducted using recipes from the Instruction Booklet, or using ingredients as specified in the standard, is within 20% of the rated power input. For additional clarification on this requirement, please contact Stuart Foster, Stuart.Foster@ul.com.



EU Enforcement Authorities to Investigate SDS Quality

January 2017 marked the launch of the fifth REACH Enforcement Project (REF-5) by EU Member States and inspectors will also be investigating the quality of Safety Data Sheets (SDS). During 2017, enforcement authorities in all EU Member States will be looking at how safety information on hazardous chemicals is compiled and communicated along the supply chain, and how it is followed in the workplace. One focus of this project is to investigate the quality of SDS containing guidelines on the safe use of hazardous substances.



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UL is an established global leader in authoring labels and SDS and our services are available via in-region regulatory expert and via an online self-service, SDS authoring tool. For more details, visit www.ulghs.com or contact Paul Deverall, Paul.Deverall@ul.com.



UL Verified Mark Program

UL Verification is an objective, science-based assessment that confirms the accuracy of a client's marketing claims. It uses an independent assessment process based on scientifically sound, repeatable methodologies to determine the validity of specific claims and can be used for products, systems or processes.

The UL verified program is being used to bring credibility to product claims and to differentiate products from those with self-declared claims. For more on this program, visit verify.UL.com or contact Ken Wilson, Ken.Wilson@ul.com.

The UL Safety Index

The UL Safety Index™ is an algorithm-based, data science initiative that provides a numerical index to quantify the relative safety of living and working environments for people in a city, state, country or region.

The UL Safety Index algorithm uses data from trustworthy organizations in the fields of economics, human development, governance, public health, and safety. Data is normalized from these diverse sources and combined into 16 indicators and 3 drivers; ultimately producing the UL Safety Index. The current version of the UL Safety Index is focused on unintentional injury.



For more details on the UL Safety Index, visit <http://www.ulsafetyindex.org>.

Customer Seminars – Wercs GHS

UL will be holding seminars on SDS compliance, chemical data management, conflict minerals, safer chemistry and sustainability solutions in March / April.

Seminars will be held in Auckland, Melbourne and Sydney, if you are interested in attending but have not yet been invited; please contact Paul Deverall, Paul.Deverall@ul.com.

Industry snippets

- o Sources within the electronics industry are noticing a shortage of copper foil, related to increased demand for copper in the manufacture of electric vehicle batteries.
- o PCB suppliers are also indicating a possible shortage of glass reinforcement, with several Chinese factories not expected to ramp glass furnaces back up after the New year shutdown.