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New European Medical Device Regulation affects textile devices

Testing and certification specialist Hohenstein supports transition to the new EU MDR.

BÖNNIGHEIM, Germany (May 25, 2021) – On May 26, 2021, medical device manufacturers will experience a sweeping change in EU regulations. The new EU Medical Device Regulation (MDR) is coming into effect after a four-year transition period. The MDR replaces the Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC). As an accredited medical device testing laboratory, Hohenstein tests the efficiency and safety of medical devices in accordance with the new regulation. Many Hohenstein test methods form the foundation for compliance assessment and documentation.

What will change under the MDR?
The new MDR is primarily directed at medical device manufacturers. The comprehensive requirements also affect the users and distributors of medical devices, such as specialists in medical supplies and pharmacies. The new MDR adopts a life-cycle approach to medical device safety, to be underpinned by clinical data and new transparency and traceability requirements.

A major change involves new reporting and documentation requirements. Previously, incident reporting affected only serious malfunctions that could cause life-threatening injuries to patients or a risk to public health. Now, reports must include all undesirable effects on patients, as well as all kinds of medical device defects and malfunctions. This includes faulty instructions.

Among other things, manufacturers must be able to point to quality management processes and risk management systems specific to the products. The new MDR also focuses stricter requirements on the reprocessing of medical devices and requires evidence of comprehensive clinical evaluations.

Hohenstein supports documentation and compliance.
Hohenstein supports the sellers and distributors of medical devices and their suppliers. Testing reports are used in technical documentation, risk evaluations and clinical assessments to ensure conformity with MDR requirements.

One of Hohenstein's specialties is inspecting Class I medical products. It is also accredited by the German National Accreditation Body (DAkkS) for testing medical face

masks to the DIN EN 14683 standard. In addition, Hohenstein laboratories analyze the performance and effectiveness of surgical gowns in accordance with DIN EN 13795, as well as compression stockings under RAL-GZ 387. To ascertain biocompatibility, Hohenstein conducts testing according to the DIN EN ISO 10993 series of standards, including cytotoxicity testing under DIN EN ISO 10993-5 and chemical characterization under DIN EN ISO 10993-18.

Hohenstein also conducts experiments and tests beyond common standards. For example, medical devices that claim health benefits require corresponding declarations.

Research and networking

The experts at Hohenstein are well connected to the medical field. One partnership with Seleon GmbH, a leading international provider of medical technology services, positions Hohenstein to support clients with regulatory affairs. In addition, the German state-owned company BIOPRO commissioned Hohenstein to moderate the formation of consortia of medical technology companies. The aim of these consortia is to develop basic documents for specific medical device groups as part of the MDR Rapid Response Program. Documents for two product groups – an orthotic seat shell and an orthopedic custom shoe – can now be ordered by emailing medical@hohenstein.com. Work in the Medical Face Mask product group has reached the implementation phase. The basic document for clinical evaluations of medical face masks will be available soon.

For further information on Hohenstein testing of medical devices, visit:
Hohenstein.US/medical-device

Details on the new European Medical Device Regulation can be found here:
Hohenstein.US/EU-MDR

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Hohenstein has been providing accredited and independent services such as testing, certification, research and development of textile-related products for 75 years.

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Manufacturers of medical devices and other stakeholders will be affected by sweeping changes in the new EU Medical Device Regulation (MDR).

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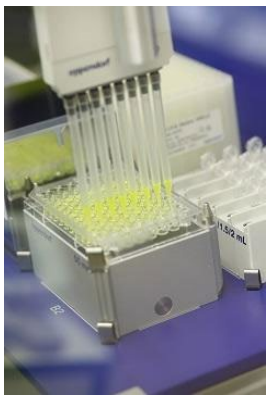

With its accredited testing laboratories for medical devices, Hohenstein is prepared to test the efficiency and safety of medical devices under the new regulation.

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About Hohenstein
With more than 40 offices and laboratories worldwide, Hohenstein is an international testing partner in the textile industry. Hohenstein's research centers around the interaction between textiles, humans and the environment. It is a founding member and leading provider of the OEKO-TEX® portfolio of services such as the STANDARD 100 by OEKO-TEX® certification, the international standard for safe textiles, and is certified by the U.S. Consumer Products Safety Commission (CPSC ID #1058) as a third-party, independent laboratory for CPSIA compliance verification. Hohenstein.US