European Union Directive 2011/65/EU, also known as RoHS II (2011/65/EU) updates legislation governing the Restriction of Hazardous Substances in electrical and electronic equipment, extending its scope to include medical devices with effect from July 22, 2014.

SGS ROHS II SERVICES FOR MEDICAL DEVICES

EXPERT IN SUPPORTING DIRECTIVE 2011/65/EU COMPLIANCE

ROHS II RESTRICTS THE USE OF CERTAIN HAZARDOUS SUBSTANCES:

- Lead (Pb) < 1,000 ppm by weight of homogeneous material

  Commonly found in solder, lead-acid batteries, cable sheathing and cathode ray tubes.
- Mercury (Hg) < 1,000 ppm

  Typically found in batteries, switches and thermostats, and fluorescent lamps.
- Cadmium (Cd) < 100 ppm

  Most often present in car batteries and pigments.
- Hexavalent Chromium (Cr VI) < 1,000 ppm

  Often used as an anti-corrosion agent in surface coatings, platings, pigments and paints.
- Polybrominated Biphenyls (PBB) < 1,000 ppm

  Commonly used as a flame retardant.
- Polybrominated Diphenyl Ethers (PBDE) < 1,000 ppm

  Commonly used as a flame retardant

KEY IMPLEMENTATION DATES

As of July 22, 2014, electrical and electronic medical devices, with the exception of implantable devices, placed onto the EU market must comply with all the provisions of RoHS II. In-vitro-diagnostic (IVD) devices containing the restricted substances at concentrations higher than the above mentioned thresholds, will not be allowed to enter the EU market after July 22, 2016.

These deadlines apply to all new medical devices placed on the market after the specified date. The same timetable applies to cables and spare parts for the repair, re-use and updating of a device's functionality, or capacity upgrade. Spare parts sold specifically for medical devices placed on the market before July 22, 2014 and in vitro diagnostic devices placed on the market before July 22, 2016.

CE

SGS

ROHS II A CE MARKING DIRECTIVE

Since 1993, the CE mark has been mandatory to show a product's compliance with an array of EU health, safety and environmental requirements. Application of the CE mark to the finished product also indicates compliance with RoHS II and all supporting CE documentation.

This means that manufacturers must complete their technical documentation and EC Declaration of Conformity in accordance with RoHS II. Technical documentation must be aligned with Module A of Annex II to decision 768/2008/EC and/or harmonised standard EN 50581 and include:

- Conformity assessment
- Use of standards
- Supplier declaration(s) of compliance
- Materials declarations
- Results of any supplier audits
- Possible testing results

All conformity assessments must include a process that demonstrates that the medical device does not contain the restricted substances, above permitted levels.

TWO ROUTES TO COMPLIANCE

Companies, including medical device manufacturers, who are newly covered by RoHS II have two primary routes to achieving compliance:

Gathering declaration of conformity and or full material composition data, from every material, component, sub-assembly supplier, outsourced design and manufacturer, and contract manufacturer along the supply chain, for every material contained in the finished product.

Having complete RoHS chemical testing performed per the IEC 62321 Standard in the event that there is a lack of supplier information or lapses in the quality or integrity of the data supplied.

ROHS II SPECIALIST SERVICES

It's clear that complying with RoHS II will be more challenging than meeting the demands of its predecessor. Whatever your challenge, SGS Consumer Testing Services is able to provide expert support for RoHS II compliance. We specialise in partial and complete testing of finished products, and offer options for non-destructive testing.

Our medical devices related services include:

- Product Risk Assessment
- Process Gap Analysis and Consulting
- Full Product and Material Testing to IEC 62321 standards
- XRF Screening
- RoHS Certificate of Conformity
- Verification Services
- Training
- REACH
- SVHC
- Ecodesign
- Energy Related Products (ErP)

WHY CHOOSE SGS?

SGS is the world's leading inspection, verification, testing and certification company. We are recognised as the global benchmark for quality and integrity. With more than 85,000 employees, we operate a network of more than 1,800 offices and laboratories around the world.

Independent and innovative, our Electrical & Electronics experts use state-of-the-art facilities and technology to deliver tailor made added value services that support improve your business. With more than 90 years experience we have a deep understanding of hazardous substances and we operate more than 28 accredited RoHS testing centres worldwide, staffed by more than 1,000 RoHS specialists.

We strive to deliver outstanding value at every step in your project by providing:

- Rapid turnaround
- Value-based pricing
- Technical assistance
- Key account management

Our expertise in compliance management will support you make the right choices for different national markets, while carrying out the necessary testing and certification quickly and professionally.

A GLOBAL REACH WITH A LOCAL TOUCH

With a presence in nearly every single region around the globe, our experts speak the local language, understand the culture of the local market and operate globally in a consistent, reliable and cost-effective manner.

CONTACT US

To learn more about SGS's certification services contact your local SGS representative, or contact our global team at ee.global@sgs.com

SGS IS THE WORLDS LEADING INSPECTION VERIFICATION TESTING AND CETIFICATION COMPANY.

WHEN YOU NEED TO BE SURE