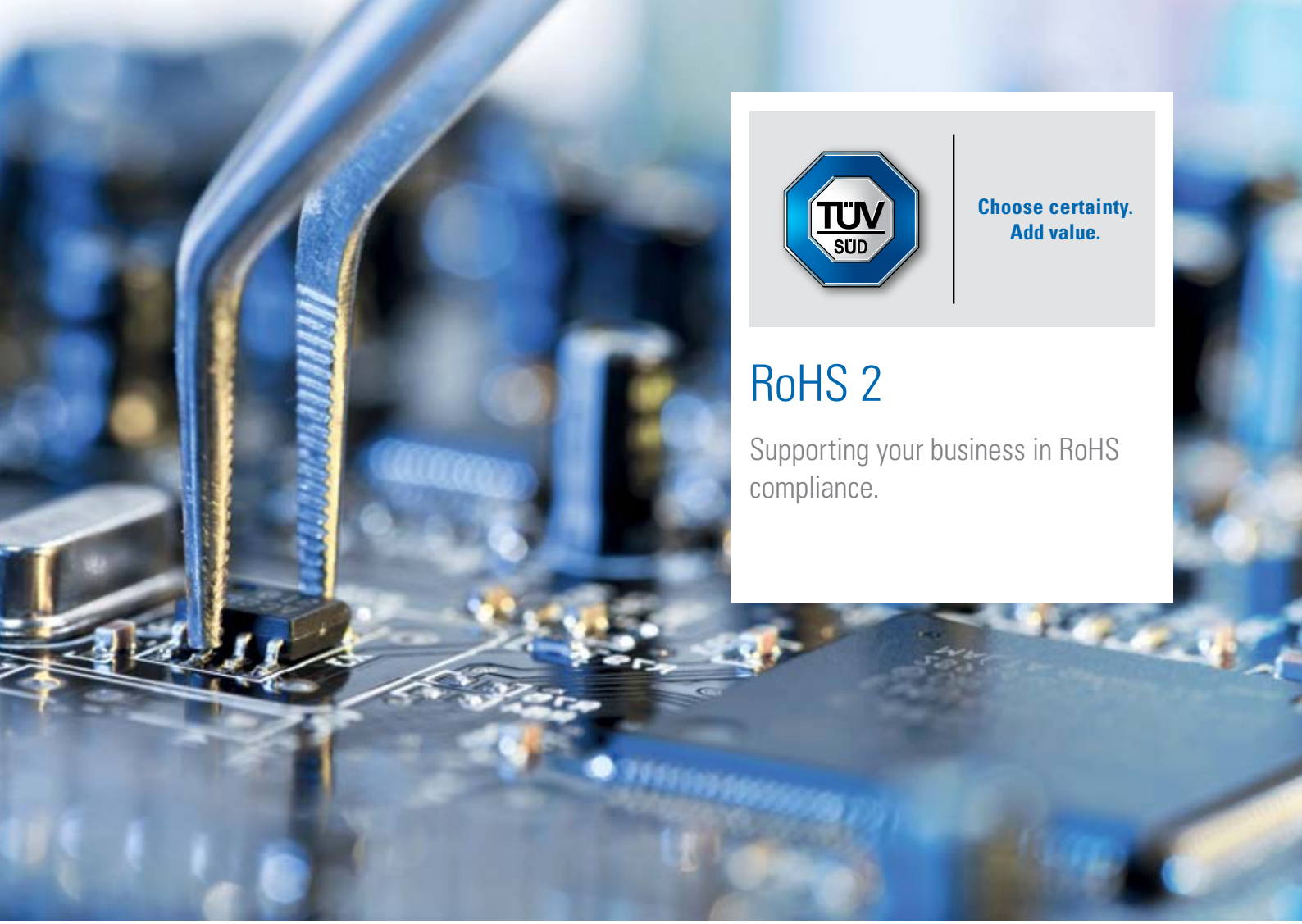


Choose certainty.
Add value.

RoHS 2

Supporting your business in RoHS compliance.

What is RoHS 2?

In 2002, the European Union first introduced the concept of RoHS – the restriction on hazardous substances in electronic and electrical equipment (EEE). Directive 2002/95/EC, which came into effect from July 2006, required the demonstration of compliance with the six restricted substances: cadmium, chromium (VI), lead, mercury, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). However, since 3 January 2013, Directive 2011/65/EU, or RoHS 2, has replaced Directive 2002/95/EC. Besides expanding the scope and clarifying some definitions, RoHS 2 is now also a CE marking Directive. It is one of the first regulations to incorporate the New Legislative Framework (NLF) for the marketing of products, which lays down obligations for all operators within the supply chain. In addition, the new Directive also ensures that additional restricted substances to be included under RoHS 2 will be coherent with other chemical regulations such as REACH.

RoHS 2 is a much more demanding piece of legislation than its predecessor, presenting new challenges for both RoHS veterans and newcomers alike.

What are the new requirements of RoHS 2?

There are five major changes in RoHS 2:

1. Scope expansion
2. Technical documentation, Declaration of Conformity (DoC) and CE marking
3. Supply chain obligations
4. Procedure for the addition of new restricted substances
5. Automatic expiry of exemptions

- **Scope expansion**
  The scope of RoHS 2 has been expanded in two ways: clarification of definition and additional product categories. The definition of “electrical and electronic equipment (EEE)” now includes all EEE that require electrical currents or electromagnetic fields to fulfil

at least one intended function. This means products that were previously excluded from the scope, such as talking teddy bears or a gas cooker with an electrical clock, are now included.

The list of product categories has also increased from the previous eight to eleven. The new categories are highlighted in bold:

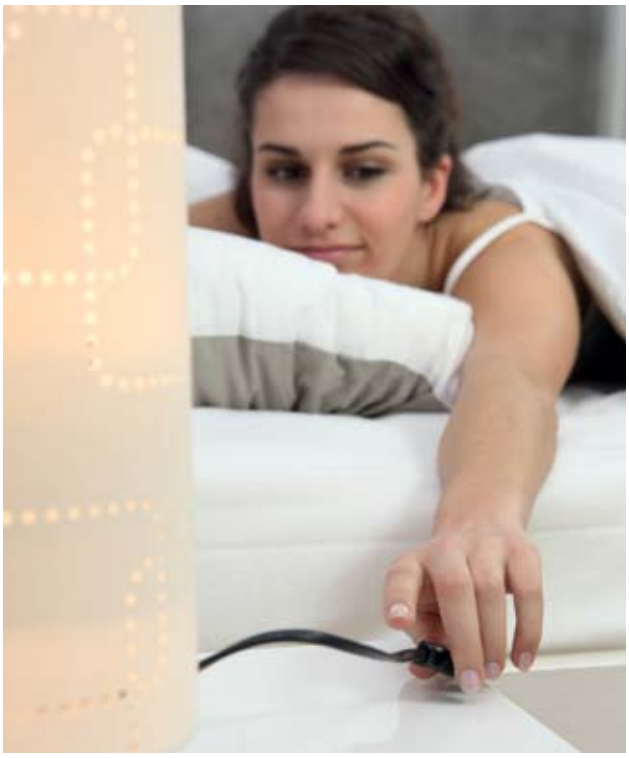
- Category 1 – Large household appliances
- Category 2 – Small household appliances
- Category 3 – IT and telecommunications equipment
- Category 4 – Consumer equipment
- Category 5 – Lighting equipment
- Category 6 – Electrical and electronic tools
- Category 7 – Toys, leisure and sports equipment
- **Category 8 – Medical devices**
- **Category 9 – Monitoring and control instruments including industrial monitoring and control instruments**
- Category 10 – Automatic dispensers
- **Category 11 – Other EEE not covered by any of the categories above**

The new product categories for medical devices, monitoring and control instruments as well as other EEE will be implemented at different times as shown in the table below.

NEW RoHS 2 SCOPE		EFFECTIVE DATE (INCLUDING DoC AND CE MARKING)
Category 8	▪ Medical devices	▪ 22 July 2014
	▪ In vitro diagnostic medical devices	▪ 22 July 2016
Category 9	▪ Monitoring and control instruments	▪ 22 July 2014
	▪ Industrial monitoring and control instruments	▪ 22 July 2017
Category 11	▪ Other EEE not covered by Categories 1 to 10	▪ 22 July 2019
Others	▪ Products that only now fall within the scope of RoHS 2, for example, due to the change in the definition of EEE.	▪ 22 July 2019

- **Technical Documentation, Declaration of Conformity (DoC) and CE marking**

  From 2 January 2013, products that fall within the RoHS 2 scope that has come into effect will require CE marking. First, the manufacturer must ensure that the product meets the restricted substance requirements and that an internal production control



has been carried out. Compliance with the restricted substance requirements must be supported by a technical documentation file in line with the general requirements in Decision 768/2008/EC. The Standard EN 50581:2012 has been published to provide guidance on fulfilling this requirement. Once these obligations have been fulfilled, a Declaration of Conformity (DoC) can be drawn up and the CE marking can be affixed on the finished product.

- **Supply chain obligations**

  RoHS 2 defines the specific obligations for each "economic operator" – the manufacturer, the authorised representative, the importer and the distributor (which includes the retailer).

  The manufacturer has to ensure that an EEE has been designed and manufactured to meet the restricted substances requirements. In addition, the manufacturer is to draw up the technical documentation, carry out the internal production control, draw up the DoC, affix the CE marking, ensure the product bears the required information for its traceability, as well as to keep the technical documentation and the DoC for 10 years after the product has been placed on the market.

  In addition, all economic operators have responsibilities for the compliance of the products they sell. For

example, manufacturers and importers are now required to keep records of non-conforming products and product recalls, and to keep their distributors informed. Upon discovery of non-conformity, they are required to apply corrective measures (including withdrawing or recalling the product) and inform the authorities immediately.

- **New restricted substances**
  When RoHS 2 became effective in January 2013, the list of restricted substances remained unchanged.

  The first review to amend this list is set to occur before July 2014 and it will cover a number of substances, including nanomaterials. In order to achieve coherence with other EU regulations, the RoHS 2 Directive includes a procedure to ensure that new restricted substances will align with other chemicals legislation, especially REACH.

- **Exemptions**
  There are now two lists of applications exempted from the substance restrictions: Annex III for all 11 categories of EEE and Annex IV for only categories 8 and 9 (i.e. medical devices and monitoring and controlling instruments). Different validity periods apply to differing categories.

  For exemptions in Annex III that are applicable to categories 8 and 9, and all exemptions in Annex IV, the maximum validity period is 7 years. Exemptions in Annex III that are applicable to categories 1 to 7 and 10 have a maximum validity period of 5 years. This means that unless an application for renewal has been submitted and approved, all exemptions will eventually expire.

  In addition to granting and renewing exemptions, any economic operator in the supply chain can also make an application to revoke existing exemptions.

Our RoHS services

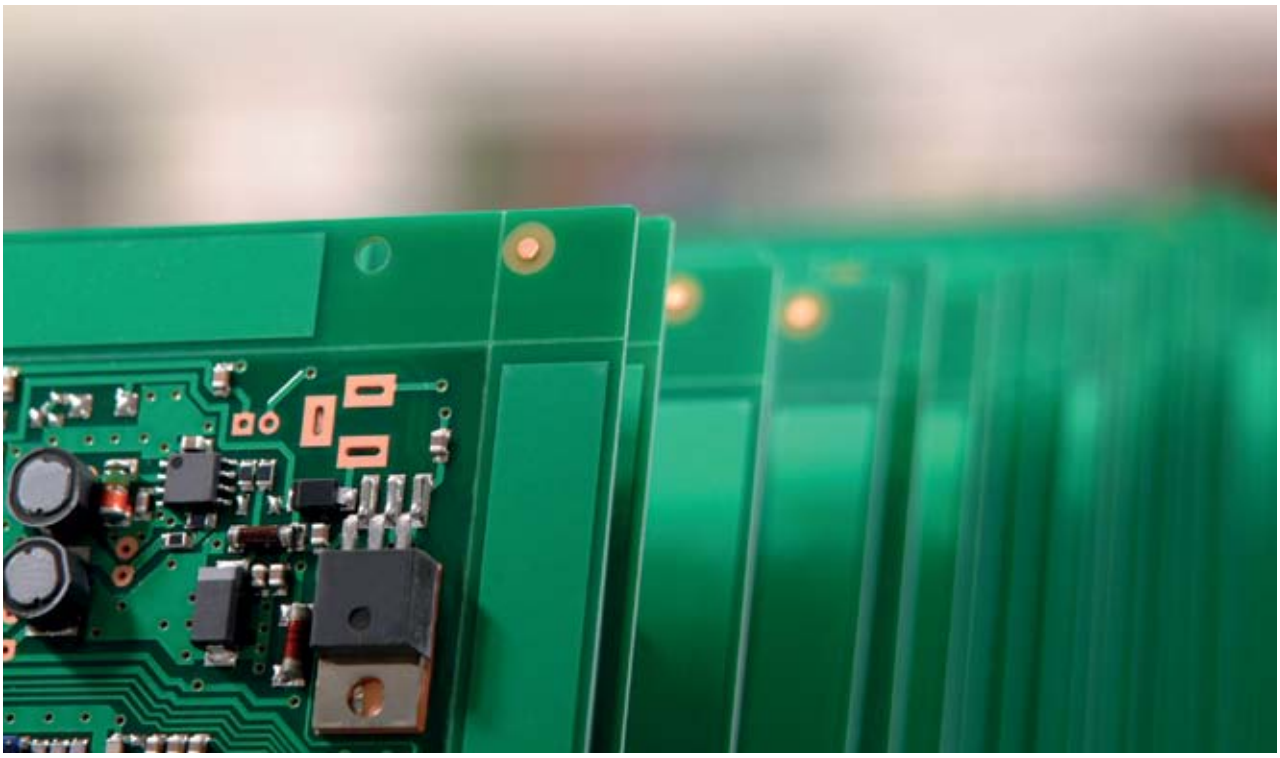
TÜV SÜD provides testing services according to relevant international standards to determine the content of hazardous substances in materials. Our testing covers materials, components, parts and finished products. We also provide screening tests in support of customers' manufacturing process. In addition to issuing the TÜV SÜD certification marks, our services include XRF (X-ray fluorescence) screening tests, chemical analysis according to EN 62321, RoHS product certification, RoHS legislation consulting and training services.

The TÜV SÜD RoHS mark

The TÜV SÜD RoHS mark attests that the product has been tested, inspected and certified in accordance with RoHS. Offered as part of our unparalleled commitment to outstanding service quality, it is a widely recognised mark that demonstrates your company is committed to quality and safety.

Your business benefits

- **Save money and time** – by ensuring that your products meet requirements, avoiding costly and time-consuming rework.



- **Minimise risk** – with independent testing to help you avoid regulatory violations and potential legal liabilities.
- **Gain a competitive edge** – by leveraging the well-known and widely trusted TÜV SÜD certification mark for your product certification.
- **Benefit from complete solutions** – with close support from our experts who can help make sense of confusing legislative requirements.
- **Gain an expert partner** – with our professional, technically qualified experts located in all your key markets.

Why choose TÜV SÜD?

TÜV SÜD is one of the largest providers of testing and certification services, with a strong reputation for independence and impartiality. We have extensive experience in certification of electrical safety for electrical and electronic (E&E) equipment, with several CB Testing Laboratories (CBTLs) under the CB Scheme. Our scope of testing and compliance is widely known throughout the industry. In addition, our marks for product tests and certification are instantly recognised by authorities and users as a clear indication that your product complies with RoHS requirements.

With an international network of laboratories and multidisciplinary experts, we offer a personalised one-stop solution designed to assist you with the complex processes and issues of RoHS compliance. Our experts have extensive knowledge and experience, and are fully versed in every aspect of the regulations. They help you meet your clients' minimum requirements and demonstrate due diligence.

Choose certainty. Add value.

TÜV SÜD is a premium quality, safety and sustainability solutions provider that specialises in testing, inspection, auditing, certification, training and knowledge services. Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering objective solutions to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Certification of electrical and electronic products
- REACH

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