# On your mark!
# For safety, quality and sustainability.

## Especially where consumers expect it from you – in international markets and sensitive environments.


Safety
Regular
Production
Surveillance

www.tuv.com
ID 6000000000

### SAFETY

Products are marketable only when they are safe and when the end users know that they are reliable. Insurers insist on measures that ensure product safety as well. To increase your competitiveness, always opt for safety testing by an independent third party institution. So be sure to let us inspect and certify your product or quality management system. Offer your customers assurance of quality and conformity with the globally recognised TÜV Rheinland test mark.

### QUALITY

The motto is „safety first“, because safety is the basis for further tests that carefully examine quality attributes such as ergonomics, ease of use, durability, ease of care or low-noise design. These requirements are based on relevant consumer demands and longtime experience in quality testing.

### SUSTAINABILITY

Sustainability means for example to reduce carbon dioxide emissions, to conserve resources and to responsibly use finite raw materials. We are committed to sustainable solutions. Our experts specialize in testing and certifying environmental friendliness and process safety. We assist companies of all kinds on their way to a resource-conserving and cost-effective orientation of their business. Whether testing for harmful substances, recyclability, energy efficiency, life cycle analysis or Green Product certification – our services will increase the trust in your products.

### MARKET ACCESS SERVICES

With our expertise in market access services, TÜV Rheinland helps you to enter new markets for your products. Our experts know all market-specific requirements for approval and offer a one-stop service – for fast access to international markets and for a quick launch of your products.

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nuremberg, Germany
Tel. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com

www.tuv.com



TÜVRheinland®
Precisely Right.

# Precision and experience are what counts.

The comprehensive product testing and certification programme for medical devices of TÜV Rheinland.



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TÜVRheinland®
Precisely Right.

# Your product merits our tests and certifications.

You can be proud of your product. Still, the requirements for safety and performance are strict. For your product to be successful and for the performance claims to be verified, the product needs to be in compliance with regard to safety, quality and suitability. We understand this. And we take care of it.

Management System
ISO 9001:2015
ISO 13485:2016
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ID 0000000027

**CERTIFICATION AND TEST MARK**

Upon successful testing and certification, the manufacturer receives a certificate and the right to use the test mark for a specified limited time. With the TÜV Rheinland test mark you show the realization and fulfillment of your quality management system according to normative requirements.

The experts from TÜV Rheinland use their extensive technical knowledge to perform tests and certifications. As the leading provider of testing and certification services in the world, we have been assisting our clients with their products for over 140 years. We stand for safety, quality and efficiency at the intersection of man, technology and environment.

We are always impartial and independent and take regulatory requirements, performance characteristics and consumer needs into account. All this greatly benefits you and your product because you reduce development costs and returns, acquire new target groups, improve customer retention, increase sales and get a faster access to international markets.

Our worldwide network of experts works together with international certification bodies and performs tests according to the applicable regulations. Product safety and product quality thus are validated. Comprehensive service, complete industry solutions with individual teams and regular contact persons support you with the development of your product from prototype to market launch. We will help you analyze demands and goals.

With tests at an early stage, you will be able to have a decisive influence on success factors.

**Our test mark helps you to market your products convincingly and credibly. Wherever in the world – TÜV Rheinland is your one-stop solution for safety and quality.**

### THE TÜV RHEINLAND TEST MARK AND CERTIPEDIA

Consumers want the guaranteed trustworthiness of an independent third party. The combination of the TÜV Rheinland test mark and the online certificate database Certipedia offers your customers an easy, fast and transparent way to review product characteristics. Certipedia is a unique platform. It shows your products and services as well as their competitive advantages at a glance. Descriptive test mark keywords convey clear messages to your customers. Thanks to the individual test mark ID and QR code, your customers can immediately see the product test specifications online. In addition, you can incorporate your test mark very effectively into your product communication strategies.

## Safety services of TÜV Rheinland – because a lot depends on your products.

The safety and quality of medical devices and in vitro diagnostics are of vital importance for patients. And with us, you are in expert hands.

In order to gain access to the European market, your products must fulfil the essential requirements.

By affixing the CE mark to your medical devices or in vitro diagnostics you testify to this and to conformity with European rules and standards. Our task is to support you throughout the conformity assessment procedure.

For over 40 years we have stood for safety and quality in the testing of medical devices - and based on the commitment, expertise and experience of our dedicated members of staff, we can offer the latest one-stop solutions for you and your products. Some of the areas covered by our services are described below:

### NEW REGULATIONS IN EUROPE FOR MEDICAL DEVICES (MDR) AND IN VITRO DIAGNOSTICS (IVDR)

The new regulations are in force. They stipulate even more rigorous and comprehensive requirements for approval of medical devices in Europe.

Perhaps you will also need the services of a Notified Body in future, because new classification rules now apply to your IVD or because you manufacture reusable surgical instruments? We would like to hear from you.

### COMPANION DIAGNOSTICS

A “Companion Diagnostic” (CDx) is used to establish if the intended medical treatment will be safe and effective for the patient. This is always based on the evidence of specific “biomarkers”. As a manufacturer in this innovative market sector, you can take full advantage of our expertise. Within the framework of your conformity assessment procedure, in future we will examine your CDx product against the requirements of the IVDR. Following successful completion of the assessment, you will be entitled to affix the CE mark to your product.

Today we can already certify your QM system to EN ISO 13485 and EN ISO 9001, in order to provide the best possible support in your preparations to meet the requirements of the IVDR.

### MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

MDSAP offers you the opportunity to fulfil the QM part of the regulations for Australia, Brazil, Japan, Canada and the USA with only one single audit. Did you know that the Canadian CMDCAS program will expire at the end of 2018? So you should prepare for the MDSAP now. We would like to tell you more.

### MEDICAL APPS

The number of Medical Apps has increased enormously in recent years. Manufacturers and providers are often not aware that their App fulfils the criteria for a medical device, and are also not aware of the implications of this. We know your products, we are close to the market and have all the latest information at hand through our work on committees with experts and official bodies. With us as Notified Body, you will have a competent partner and you can feel truly confident.

### CYBERSECURITY & WIRELESS

Increasing use of IT and wireless applications in the area of medical devices has led to increased risk of cyber attack. This means that the information and data security of a medical device can be severely compromised. In the worst case, this can lead to negative impacts on the function, or even total failure. Therefore it is essential to protect defibrillators, pacemakers and also mobile devices such as tablets and smartphones against potential misuse by unauthorised third parties. As a leading service provider in the area of IT security, we can offer you the complete package, from analysis and optimisation up to testing and certification of the information security of your products.

**WITH US YOU ARE ALWAYS UP TO DATE.**

TÜV Rheinland Information Days: Information regarding innovations, changes and trends in the field of medical devices can be found at www.tuv.com/events.

### BIOCOMPATIBILITY

Our biological testing and assessment of the biocompatibility of medical devices, biomaterials and materials in general can indicate what reactions are likely to be caused in the patient through product contact, and if the resulting risk potential is tolerable or not. Reduce the likelihood of expensive development failures through in vitro testing of cell and blood compatibility or tests to establish the presence of extractable matter, and exclude risk to patients from the very beginning.

Our comprehensive range of services includes tests according to the ISO 10993 series of standards, creation of test strategies including risk assessment, and also the selection of special test procedures for production monitoring following CE marking, for validation of cleaning processes and for inspection of reprocessable medical devices.