Are you looking for a partner who provides reliable support?
Then come to us – We are a “Notified Body” for all medical products and in-vitro diagnostics.
We certify products and QM systems for the European and other international markets.
We provide you with extensive experience, in-depth expertise and comprehensive service.

Quality is Vital - Trust Us!
## Testing and Certification Services for the European Market

TÜV Rheinland is your one-stop source for all testing and certification needs. We perform conformity assessments to all European Medical Device Directives (MDD, IVDD, AIMDD) for CE Marking (CE 0197). We are accredited by OSHA as a NRTL, and by the Standards Council of Canada for testing and certification to a wide variety of standards. TÜV Rheinland is Accredited under the FDA 510(k) Third Party Review Program.

### Services at a glance

<table>
<thead>
<tr>
<th>CE conformity for active and non-active medical devices</th>
<th>CE conformity for in-vitro diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>As a manufacturer you must declare the conformity of your medical products with the requirements of the medical directives with the CE mark. Depending on the product’s risk category, the involvement of a Notified Body, which you commission, for example, for conducting an EC type-examination, the assessment of a design dossier or the auditing of your QM system, is essential. In cooperation with you, we conduct the necessary compliance assessment for your company and products. You are thus quickly provided with your “admission ticket” to the countries of the EU.</td>
<td>We are a “Notified Body” for the area of in-vitro diagnostics (IVD). You can have your products tested and certified by us in accordance with the various procedures of the European IVD Directive.</td>
</tr>
</tbody>
</table>

### GM mark – a visible display of value add

The GM mark is a comprehensive quality and safety statement by a neutral, independent testing authority. Assure your customers that you are doing more than what is absolutely necessary in order to guarantee the safety and quality of your products.

### Service Scope for Medical Products

#### Quality Management System Certification
- ISO 9001
- ISO 13485
- ISO 13485 under CMDCAS (Canadian Medical Devices Conformity Assessment Scheme)

#### Medical Product Safety Testing and Certification
- CB Report and Certification
- GM Mark
- TÜV Mark
- CoC (Certificate of Conformity)
- cTÜVus Mark
- TÜV Test Report
- JIST 0601-1 Test Report (For Japan)

#### Others
- PAL (Pharmaceutical Affairs Law)
- Medical Product Certificate for Japan
- FDA 510(k) Third Party Review
- EMI/EMC Testing & Certification
- IP Tests
- Wireless Testing & Certification
- Market Access Services
- NABL accredited test lab for EMI/EMC & safety testing
EU Regulation for Medical Devices

**EU Member Countries**
The extended law on Medical Devices developed by the European Union (EU) regulates the free movement of medical devices within the EU. Manufacturers exporting to the EU have to conform to EU’s Medical Directives (AIMDD: 90/385/EEC, MDD: 93/42/EEC and IVDD: 98/79/EC). Manufacturers also need to affix the CE Mark to show compliance to the MDD, AIMDD & IVDD is mandatory. TÜV Rheinland can help manufacturers meet the requirements of the EU’s Medical Directives by assessment to the full scope of these directives.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Directive</td>
<td>Date of Directive</td>
<td>Applicable Date</td>
</tr>
<tr>
<td>Aimdd</td>
<td>Jun. 20, 1990</td>
<td>Jan. 01, 1993</td>
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<tr>
<td>Classification</td>
<td>Jan. 01, 1995</td>
<td>Dec. 07, 2003</td>
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<tr>
<td>N/A</td>
<td>Class I, IIa, IIb, III</td>
<td>List A, List B, Self-testing, Performance Evaluation, Others</td>
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<tr>
<td>Quality Management System</td>
<td>Quality Management System for Medical Products ISO 9001, ISO 13485</td>
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<tr>
<td>Safety Requirement</td>
<td>Essential Requirements (In the Directive Annex I)</td>
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<tr>
<td>Risk Analysis/Assessment</td>
<td>Risk Analysis/Assessment (ENISO 14971)</td>
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<tr>
<td>Clinical Evaluation/Investigation</td>
<td>Clinical Evaluation/Investigation (EN 540/ISO 14155)</td>
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<tr>
<td>Labelling (Annex I, EN 980, EN 1041, EN 1658,EN 15986)</td>
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<tr>
<td>Other Applicable Standards (e.g.EN 60601-1)</td>
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<td>Market Information</td>
<td>Information Feedback System</td>
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<td>Post-Market Surveillance</td>
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<td>Customer Complaint Investigation</td>
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<td>Vigilance System</td>
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<td></td>
<td>Advisory Notice (Recall)</td>
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</tbody>
</table>

**Medical Product Approvals**

- TÜV BAUART
- EMC Mark
- CE Marking (Notified body)
- System Certification Mark

www.ind.tuv.com
North America (USA and Canada)

TÜV Rheinland of North America is a Nationally Recognized Testing Laboratory (NRTL) in the United States. It is also accredited by the Standards Council of Canada to test and certify electro-medical products to Canadian National Standards. Medical device manufacturers can demonstrate compliance for U.S. and Canadian markets through a single mark – cTÜVus – on product(s). Having this mark on your product(s) would denote compliance to U.S. and Canadian National Standards. TÜV Rheinland’s test laboratories across Asia are included in this scheme, thereby making it possible to test your medical equipment outside the U.S. and Canada for your convenience.

Use of CB Scheme, Global Passport
The CB Scheme provides you the convenience of ‘one product, one test, one mark wherever applicable.’ CB is the abbreviation for certification body. The CB scheme is based on the mutual recognition of tests and certificates among several National Certification Bodies (NCBs). The document of reference is the CB Test Certificate in conjunction with the relevant test report. The members of the CB scheme issue a CB Test Certificate in connection to the test report. Based upon this certificate and report, other CB members will issue licenses for their national level. Consequently, the complete approval test does not need to be repeated for each country. Our testing laboratories are accredited as CB testing laboratories.

CB scheme: http://www.cbscheme.org

The TÜV Rheinland Group worldwide.

- Founded in 1872
- At 500 locations in 65 countries
- More than 18000 employees
- More than 2,500 services across all sectors
- More than 39 industries across 6 business streams

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