TARGET CONFORMITY MANAGEMENT SERVICES

Target Conformity Management Services (TCMS) is one of the leading Technical Service Provider in the field of Product Certification, Quality Management System Certification, Testing and Trainings. With professionals having hands on experience in almost all the regulations which we serve imparts not only the value addition but also provides options to look into the future needs while meeting the regulatory requirements at all point of time.
A team of highly skilled engineers and having an alliance with Notified Body Technicka Inspekcia, Slovakia, a.s 1354 provides services for Product certification, Welder Approval and Quality Management System. Technicka Inspekcia a.s (TI) is a Joint stock company registered in Slovakia and is a Notified Body with full scope of certification. TI is a permanent member of CEOC International (CEOC international is an international organization which brings together different inspection & certification bodies to promote better, safer and more environment friendly products in the market).

We are offering one stop solutions including in the following areas:

- **Product Certifications (CE Marking):**
  - ATEX (2014/34/EU) Certification
  - Low Voltage Directive (2014/35/EU)
  - Machinery Directive 2006/42/EC)
  - Pressure Equipment Directive (2014/68/EU)
  - Medical Device Regulation EU (2017/745)
  - In-Vitro Medical Device Regulation EU (2017/746)
  - Personal Protective Equipment Regulation EU (2016/425)
  - Construction Products Regulation EU (305/2011)

- **CUTR (EAC) Certification:** EAC or EurAsian Conformity is the term used to indicate compliance in the EurAsian Economic Union (EEU) that consists of Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan.

- **Trainings:**
  - Understanding the Requirement and Internal Auditor of ISO 9001:2015, ISO 13485:2016, ISO 14001:2015 & ISO 45001:2018,
  - Understanding the Requirement of ISO 14971 Risk Management- Medical Devices,
  - Understanding the Requirement of IATF 16949:2016 - Automotive Quality Management System,
  - Understanding Potential Failure Mode Effect Analysis (PFMEA),
  - Understanding Statistical Process Control (SPC) and Associated Tools,
  - Understanding the Requirement of ATEX Directive 2014/34/EU; Equipment for Potentially Explosive Atmospheres,
  - Understanding the Requirements of ISO/IEC 80079-34:2019; Quality System to Manufacture Ex Equipments including Protective Systems,
  - Understanding Qualification of Welders and Welding Procedure Approval,
  - Customized Training as per the requirements.

- **Third Party Inspection**

- **Testing:**
  - Safety Testing as per EN/IEC Standards,
  - Explosion Proof Testing as per EN 60079 series,
  - EMC Testing,
  - Personal protective Equipment Testing.

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Machinery Directive

We at TCMS in alliance with our partner Technicka Inspekcia, a.s Slovakia having full scope to certify all products falling under Machinery Directive (2006/42/EC).

This Directive applies to all machinery and safety components. A machine is defined as "an assembly of linked parts or components, at least one of which moves.". There are exclusions such as military equipment, machines which are already covered by other, more specific, directives and equipment which falls within the scope of the Low Voltage Directive.

The essential protection requirements demand that machine manufacturers identify the hazards that their products contain and assess the risks these hazards present to users. Any risks identified must be reduced to as low a level as is practicable. Detailed requirements are laid out in a series of safety standards. The administrative provisions of the Directive require manufacturers to produce a Technical File, sign a Declaration of Conformity and label the product with certain markings.

Annex IV contains a list of about 15 types of machine which are subject to special procedures. These must either be made fully in accordance with the provision of the standard, or be subjected to type examination by a Notified Body.

TCMS Can offer:

- Product Evaluation and Gap analysis.
- Testing as per harmonized, international, national standards, or client's own specification.
- Technical file review
- Risk Assessment
- Issuance of Certificate
- Annex IV Notified Body Certification.
- Design Review
- Issuance of Certificate

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ATEX DIRECTIVE (2014/34/EU)

ATEX Directive 2014/34/EU covers equipment and protective systems intended for use in potentially explosive atmospheres. The directive defines the essential health and safety requirements and conformity assessment procedures, to be applied before products are placed on the EU market.
The directive places responsibilities on the manufacturer of these products. The main responsibility of the manufacturer is to prevent the formation and ignition of explosive atmospheres. This may be achieved by using one of the well-established protection concepts (such as flameproof protection, or intrinsic safety), or by proving compliance directly against a set of 'essential health and safety requirements', which are given in the directive. Under ATEX you can put the product in the market once you have successfully achieved EU type Examination and Quality Assurance Notification (QAN).

This directive defines following product groups for use in potentially explosive atmospheres:

- **Electrical and non-electrical equipment**
- **Electrical and non-electrical protective systems**
- **Electrical and non-electrical components**
- **Electrical and non-electrical safety devices**

We at TCMS in alliance with our partner Technicka Inspekcia, a.s Slovakia having full scope to certify the products falling under ATEX directive.

EU Type Examination: Type Examination requires the products to be tested as per the requirements of the ATEX Harmonized Standards. Based on the Intended Use and application of the product standard for testing as per EN 60079 series shall be Tested. Certificate under EU type is normally valid for 10 years.

Quality Assurance Notification: to put the product on the market, the manufacturer must hold a valid Quality Assurance Notification (QAN), under this it basically cover the Quality Management System to be maintained by the manufacturer as per EN 80079-34 for the Ex products. It requires an onsite audit and an annual surveillance audit with issuance of limited time certificate for 12/18 months.

ATEX For Non-Electrical Products: For Non-Electrical Products which fall into Category 2 & 3 an EU type Examination is not required. For category 2 Non-Electrical Equipment, the technical file shall be submitted to the notified body and shall be archived/stored with Notified body for 10 years. An acknowledgment for archive of technical file will be issued by Notified Body, under this the technical file is not reviewed by the Notified Body.

We have full scope under ATEX and can provide:

- **EU Type Examination**
- **Quality Assessment Notification**
- **Testing Services as per EN 60079 series (for Electrical Product) and EN 80079 series (for Non-Electrical Product)**
- **Unit Verification**
- **Technical File Archive (for Non-Electrical Products)**

Advantages with TCMS as your Certification Partner:

- Pragmatic Approach to Reduce Project Timelines and Cost,
- One Stop Service for all Needs, Certification & Testing,
- Design Review as per applicable EN Standards,
- Design guidance as per applicable protection concepts,
- Full Scope under ATEX and Localized Auditor.

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LOW VOLTAGE DIRECTIVE (2014/35/EU)

European Union's Low Voltage Directive (LVD) ensures that electrical equipment within certain voltage limits includes protection against electric shock and other hazards. Manufacturers and distributors who wish to sell electrical equipment in the European Economic Area must certify that their products comply with relevant regulations. On approval, they can apply a CE Mark to their products, which permits their sale anywhere within the EU and EEA.

Products are presumed to conform to the safety objectives of the LVD where the equipment has been manufactured in accordance with a harmonized standard. Alternatively, the manufacturer may construct the product in conformity with the essential requirements (safety objectives) of the LVD, without applying harmonised, international or national standards. In such a case the product will not benefit from presumption of conformity and therefore the manufacturer must include in the technical documentation a description of the solutions adopted to satisfy the safety aspects of the Directive.

The LVD covers health and safety risks on electrical equipment operating with an input or output voltage of between:

- **50 and 1000 V for alternating current**
- **75 and 1500 V for direct current**

It applies to a wide range of electrical equipment for both consumer and professional usage, such as:

- **household appliances**
- **cables**
- **power supply units**
- **laser equipment**
- **certain components, e.g. fuses**

EU legislation in the electrical sector is important to ensure that health and safety requirements are the same across Europe for products placed on the market.

Before a product is placed on the market the following must be done:

- The manufacturer must compile a technical documentation to assess whether the product complies with the directive
- The manufacturer must draw up a 'declaration of conformity'.
- The manufacturer must affix the CE marking

TCMS can offer:

- Advice on the standards applicable to products,
- Testing as per harmonised, international, national standards, or client's own specification,
- Assessment for compliance with the LVD,
- Assessment of the technical documentation,
- Issuance of CE Certificate.

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PRESSURE EQUIPMENT DIRECTIVE (2014/68/EU)

The European Pressure Equipment Directive (PED) 2014/68/EU came into force on 20 July 2016. The Pressure Equipment Directive (PED) (2014/68/EU) applies to the design, manufacture and conformity assessment of stationary pressure equipment with a maximum allowable pressure greater than 0.5 bar

Why apply the PED?

Legislation across the EEA requires that all applicable items of pressure equipment must be fully compliant with the PED. As a result, manufacturers must revise their working practice and develop the appropriate Technical Files for their full product range. The PED encompasses design verification, material selection, manufacturing/fabrication practices and qualification, product testing, product marking and user instruction compilation.

Scope of the directive:

With a pressure housing with a maximum pressure greater than 0.5bar is defined as Pressure Equipment. Pressure Equipment directive covers following equipments:

- Pressure Vessels,
- Pressure accessories,
- Safety Accessories,
- Piping
- Industrial Valves,
- Steam Generators,
- Heat Exchangers,
- Reactors, etc.

We at TCMS in alliance with TI have the capability to cover all aspects for PEDs conformity assessment modules which includes:

- Product Inspection & certification
- Material Approval
- Type Examination
- Quality System Approval
- Welder Approval
- Unit Verification (Module G)

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Personal Protective Equipment (EU) 2016/425

We at TCMS in alliance with Notified bodies have full scope to certify the products falling under PPE Regulation (EU) 2016/425. Personal Protective Equipment (PPE) is defined as any device intended to be worn or held for protection from injury. In Europe, placing PPE products on the market is regulated by Regulation (EU) 2016/425.

PPE Regulation (EU) 2016/425 has replaced the PPE Directive 89/686/EEC in April 2018, covers the manufacturing of PPE to ensure the highest level of protection. The CE mark on PPE is an evidence that the PPE Complies with relevant standards and are safe for use.
Our expertise in assessing Personal Protective Equipment manufacturers around the world to test and certify their products. Our experienced Certification team can assist manufacturers in choosing the correct procedures and test methods for their products, and provide guidance on aspects of the type-examination such as Technical File content, Labelling, and User Information.

PPE Category wise Requirement:

Category	Requirement	Applicable Modules
Category I	Internal Production Control a process that requires the development of a technical file which includes the manufacturer's Declaration of Conformity.	Internal production control (module A)
Category II	EU-type examination by a Notified Body.	EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C)
Category III	EU Type Examination certificate and ongoing assessment of compliance. Audit the manufacturing site annually to ensure that quality management systems are in place.	EU type-examination (module B) set out in Annex V, and either of the following: • conformity to type based on internal production control plus supervised product checks at random intervals (module C2); • conformity to type based on quality assurance of the production process (module D)

TCMS can offer:

- Assistance in choosing the correct procedures and test methods for their products,
- guidance on aspects of the type-examination such as Technical File content, Labelling, and User Information,
- Technical File review & Gap Analysis,
- Testing of the products as per EN Standards,
- Issuance of EU type Examination Certificate.

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