

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## Requested standard

- |  |   |  |
|--|---|--|
| <input type="checkbox"/> DIN EN ISO 9001 (page 1-3)    | <input type="checkbox"/> IATF 16949/VDA 6.2 (page 1-3)  | <input type="checkbox"/> ISO 27001                   |
| <input type="checkbox"/> DIN EN ISO 14001 (page 1,2,4) | <input type="checkbox"/> ISO 50001 (page 1,2,5)         | <input type="checkbox"/> BS OHSAS 18001 (page 1,2,6) |
| <input type="checkbox"/> SCC/SCP (page 1,2,7)          | <input type="checkbox"/> PROFiCERT-product (page 1,2,8) | <input type="checkbox"/> PROFiCERT-plus (page 1-2)   |
| <input type="checkbox"/> ECOSYS (pages 1-3,4,6)        | <input type="checkbox"/> ISO 13485 (pages 1-3, 9-10)    | <input type="checkbox"/> _____                       |

## Contact TÜV Hessen:

name: \_\_\_\_\_

## Organisation / Main location

Registered company's name: \_\_\_\_\_

Corporation member: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone / FAX: \_\_\_\_\_ / \_\_\_\_\_

Information about employees for more than 3 locations use next sheet	Main location / Headquarter	Location 2: _____	Location 3: _____
Number of employees:			
Thereof apprentices:			
Thereof part-time employees:			
Thereof employees, that work on similar activities (e. g. production line, Call center)			
Employees in shift work:			
Amount of shifts:			
Number of temporary workers:			

## Management / Leader

Name: \_\_\_\_\_ E-Mail: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

## Management representative

Name: \_\_\_\_\_ E-Mail: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



**Scope of application / Scope of management system** (e.g. Development, production and sales of products)

---

---

---

**Products / Product groups / Services**

---

---

---

**Main production process**

---

---

---

**External consultation for Management system by:**

Name: \_\_\_\_\_

Existing or previous Certifications			
Norm:	Certificate valid to:	Certification body:	Last audit day of initial / or Re-Cert

**Individual comments**

---

---

---

**For correctness of data of all information in this questionnaire**

\_\_\_\_\_  
Location; Date

\_\_\_\_\_  
Stamp/Signature

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## Only for standard 9001 / IATF 16949 / VDA 6.X / ISO 13485

### Not relevant requirements (ISO 9001: 2015)

(for IATF 16949 / VDA 6.X only the product-/ service development may be excluded)

---



---



---

For more than 3 locations use next sheet	Main location / Headquarter	Location 2: _____	Location 3: _____
<b>Products / Product-groups / Services</b>			
<b>Self-evaluation of Risk Category:</b> <b>High</b> (failures may lead to catastrophe or may endanger life)  <b>Medium</b> (Failure may lead to injuries or diseases)  <b>Low</b> (injuries or diseases are unlikely)			
<b>Automotive Clients including the individual OEM supplier no.</b>	(important for IATF 16949 / VDA 6.X)		
<b>Outsourced processes to external suppliers</b> (Keywords: extended workbench, logistic...)	(important for IATF 16949 / VDA 6.X)		
<b>Supporting functions , that are executed in other locations</b>	(important for IATF 16949 / VDA 6.X)  If relevant, number of supporting employees: _____	If relevant, number of supporting employees: _____	If relevant, number of supporting employees: _____

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## For standard ISO 14001

For more than 3 locations use next sheet	Main location / Headquarter	Location 2: _____	Location 3: _____
<p><b>Machinery / production processes including special environmental relevance</b></p> <p>(e. g. electroplating, painting, wastewater treatment plant)</p>			
<p><b>Specific regulatory requirements</b></p>			
<p><b>Self-assessment of environmental relevance:</b></p> <p><b>High</b> (Great amount of vast and heavy environmental aspects)</p> <p><b>Average</b> ( <u>moderate</u> env. aspects)</p> <p><b>Low</b> (Low amount of light env. aspects)</p> <p><b>Limited</b> (Very low amount of env. aspects)</p>			

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## Only for norm ISO 50001

For more than 3 locations use next sheet	Main location / Headquarter	Location 2: _____	Location 3: _____
<b>Amount of energy consumption</b>	<input type="checkbox"/> < 55,500 MWh <input type="checkbox"/> 55,500 – 555,500 MWh <input type="checkbox"/> > 555,500 MWh	<input type="checkbox"/> < 55,500 MWh <input type="checkbox"/> 55,5 – 555,500 MWh <input type="checkbox"/> > 555,500 MWh	<input type="checkbox"/> < 55,500 MWh <input type="checkbox"/> 55,5 – 555,500 MWh <input type="checkbox"/> > 555,500 MWh
<b>Type of energy (in MWh)</b> Only external energy sources are relevant; Steam, for example, is produced via externally-related natural gas in its own steam boiler, Only natural gas is to be ticked / relevant If steam or, for example, compressed air is obtain externally to, these energy types are / are to be crossed / relevant	<input type="checkbox"/> Electricity _____ <input type="checkbox"/> Natural gas _____ <input type="checkbox"/> Heating oil _____ <input type="checkbox"/> Steam _____ <input type="checkbox"/> (Distance)Heat _____ <input type="checkbox"/> renewable energies (e.g. Biogas) _____ <input type="checkbox"/> Compressed air _____ <input type="checkbox"/> _____	<input type="checkbox"/> Electricity _____ <input type="checkbox"/> Natural gas _____ <input type="checkbox"/> Heating oil _____ <input type="checkbox"/> Steam _____ <input type="checkbox"/> (Distance)Heat _____ <input type="checkbox"/> renewable energies (e.g. Biogas) _____ <input type="checkbox"/> Compressed air _____ <input type="checkbox"/> _____	<input type="checkbox"/> Electricity _____ <input type="checkbox"/> Natural gas _____ <input type="checkbox"/> Heating oil _____ <input type="checkbox"/> Steam _____ <input type="checkbox"/> (Distance)Heat _____ <input type="checkbox"/> renewable energies (e.g. Biogas) _____ <input type="checkbox"/> Compressed air _____ <input type="checkbox"/> _____
<b>Description of essential energy consumer</b> (e. g. Plastic injection machineries, hardening and heat treating plant,....)			
<b>EnMS relevant no of employees</b> 1. TOP Management, ENMR and Members of energieteam; 2. Other persons responsible for the effectiveness of the EnMS / Managers with influence on energy consumption; (eg area / department manager, plant manager). (No multiple counting for employees with several relevant functions)	1. _____  2. _____	1. _____  2. _____	1. _____  2. _____
<b>Energy production</b>	Is energy produced at the location? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, by which system:	Is energy produced at the location? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, by which system	Is energy produced at the location? <input type="checkbox"/> yes <input type="checkbox"/> no If yes, by which system:

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## Only for standard BS OHSAS 18001

For more than 3 locations use next sheet	Main location / Headquarter	Location 2: _____	Location 3: _____
<b>Class of hazard and Employer's Liability Insurance Association (where applicable)</b>			
<b>Main risks/ Endangering in work-/health-protection</b> (e. g. hazardous materials, dangerous work equipment/ machinery, Environment)			
<b>Special awards/ recognitions in working-/health-protection for;</b> (if yes, please specify)			
<b>Self-assessment of risk relevance**:</b> <b>High</b> ( <u>vast and heavy</u> accident risk) <b>Average</b> ( <u>moderate</u> accident risk) <b>Low</b> ( <u>low</u> accident risk) <b>Limited</b> ( <u>Very low</u> accident risk)			

### \*\*Explanations for self-assessment of risk relevance:

**Limited** Insurance-/Consulting companies; business and managing activities

**Low** Trading, Hotels and restaurants

**Medium** producing area/processes ,e.g. chemical plants with physical/chem. mixing process, paper manufacturers, Glass- and ceramic industries, surface treatment, manufacturer of motor- and other vehicles, Assembly process of metal- and electro-/electronic-industry, Steam powered boilers, pressure vessels, manufacturer of plastic- and rubber parts, metal forming

**High** Mining, tunneling, electro technical installations, facilities with high risk potential, facilities that use chemicals (Major Hazard Facility), high pressure gas pipelines, facilities in areas of explosive materials, Acetylene plants, facilities for high amount of combustible liquids, handling of hazardous materials (asbestos, pyrolysis, cancer- and genetic material changing materials, fumigations, pest control, activities with biological based materials, work with ionizing radiation

**Single case tests are necessary for enterprises that are handling with atomic issues like nuclear power stations etc.**

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## Only for standard SCC/SCP

For more than 3 locations use next sheet	Main location / Headquarter	Location 2: _____	Location 3: _____
<b>Average number of employees* in certified sector (including part-time employees, apprentices and trainees!)</b>			
<b>Number of projects in certificating extent** (Visiting of projects in SCC-Audits are necessary!)</b>			
<b>Special awards/ recognitions in working-/health-protection for; (if yes, please specify)</b>			

\* **Average amount of employees** = Employees within calender-/ fiscalyear divided by regular working time in concern

\*\* **Investigation of the amount of projects in the certification extent** = average number of construction sites, workshops, or production areas per day within the whole year, **or** actual number of construction sites, workshops, or production areas, that the certified enterprise is working on, while being tested.  
Construction sites, workshops, or production areas, that are leaded by on direction, may be summarized to one project.  
This also counts for similar activities with low production stage.

## Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



### Only for TÜV PROFiCERT-product

Detailed statements according to the products:

- Following products/ product-groups (*only possible for products, that don't need a CE-label.*) will be included :

**Individual products (for >5 e.g.)**

Product designation	Amount/ year	Price net	Legal requirements for the product

**Product-groups (similar products, e.g. different size, color, etc.)**

Product designation	Amount/ year	Price net	Legal requirements for the product

Refer to attachments, if needed.

*Example: Product-group Pencil metal, Quantity ca. 20 million/a, requires DIN.../ISO...*

- Average production depth for above products in the Enterprise:

≤ 10%

11% ≤ x ≤ 30%

> 30%

- Product inspection process is documented in the companies procedures

yes

no



# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



## Only for standard ISO 13485

Detailed statements according to the service / manufacturing / product groups and classification

<p><b>Process of manufacturing / service</b></p>	<p><input type="checkbox"/> manufacturer</p> <p><input type="checkbox"/> supplier / manufacturer / manufacturer of components</p> <p><input type="checkbox"/> retailer</p> <p><input type="checkbox"/> service organisation      type of service _____</p> <p><input type="checkbox"/> others _____</p> <p><input type="checkbox"/> sterilisation method</p> <p>    <input type="checkbox"/> ethylene oxide   <input type="checkbox"/> moist heat   <input type="checkbox"/> radiation   <input type="checkbox"/> aseptic processing</p> <p>    <input type="checkbox"/> other _____</p> <p><input type="checkbox"/> custom made devices:   <input type="checkbox"/> sterile   <input type="checkbox"/> non sterile</p> <p>    <input type="checkbox"/> ophthalmic optics</p> <p>    <input type="checkbox"/> dental technology</p> <p>    <input type="checkbox"/> hearing device</p> <p>    <input type="checkbox"/> orthopedic- und orthopedics shoe</p> <p>    <input type="checkbox"/> rehab technology</p> <p>    <input type="checkbox"/> medical supply store</p>
<p><b>Product groups</b></p>	<p><b>non-active medical devices</b></p> <p><input type="checkbox"/> general non-implantable medical devices</p> <p><input type="checkbox"/> implants</p> <p><input type="checkbox"/> devices for wound care</p> <p><input type="checkbox"/> dental products</p> <p><input type="checkbox"/> _____</p> <p><b>active non-implantable medical devices</b></p> <p><input type="checkbox"/> general active medical devices</p> <p><input type="checkbox"/> devices for imaging</p> <p><input type="checkbox"/> monitoring devices</p> <p><input type="checkbox"/> devices for radiation therapy and thermo therapy</p> <p><input type="checkbox"/> _____</p> <p><b>active implantable medical devices</b></p> <p><input type="checkbox"/> general active implantable medical devices</p> <p><b>vitro diagnostic medical devices</b></p> <p><input type="checkbox"/> In Vitro Diagnostic Instruments, devices and software</p> <p><input type="checkbox"/> _____</p>

# Questionnaire for Certification Preparation

FAX: +49 6151 600336 / E-Mail: proficert@tuevhessen.de



page 10 of 10

**Exact risk classification / description of products / services / main manufacturing process / Product-groups**

**Critical supplier:**

critical supplier	location	process / components

**Language:**

German:

English: