

# Questionnaire for Certification Preparation

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



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## 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"/> Client specific (page 1,2) |
| <input type="checkbox"/> DIN EN ISO 14001 (page 1,2,4) | <input type="checkbox"/> ISO 50001 (page 1,2,5)         | <input type="checkbox"/> PROFICERT-plus (page 1-2)  |
| <input type="checkbox"/> SCC/SCP (page 1,2,7)          | <input type="checkbox"/> PROFiCERT-product (page 1,2,8) | <input type="checkbox"/> ISO 45001 (Seiten 1, 2, 6) |
| <input type="checkbox"/> ECOSYS (pages 1-3,4,6)        | <input type="checkbox"/> ISO 13485 (pages 1-3, 9-10)    | <input type="checkbox"/> according _____            |

## Contact TÜV Hessen:

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

## Organisation / Main location:

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

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

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

Business reg. no.: \_\_\_\_\_

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

Information about employees for more than 3 locations use add. sheet	Location 1/ Headquarter	Location 2:	Location 3:
Number of employees (without temporary workers):			
Thereof part-time workers:			
Thereof apprentices:			
No. of part-time workers:			
Thereof employees who perform the same / similar, simple tasks with similar, low safety risks (e.g. assembly line, call centers, remote sales employees/drivers)			
Employees in shift work:			
Amount of shifts:			

### \* To be completed only for companies with several locations (concerns requirements for multi-site)

- A defined central function with responsibility for the MS exists.
- The central function has the organizational authority to structure, implement and maintain the management system.  
It also has a contractually guaranteed operational right of access to all locations.
- The management system is subject to a centralized assessment.
- All sites included in the organization's internal audit program

### Affects additional prerequisites for a sampling procedure

- The value-added processes at all locations are of the same nature and run according to similar methods.  
and processes from or are interconnected with each other.

### For combined processes (synergies with several standards)

- complete integration in MS documentation and practical implementation; essential contact persons are identical!

## Gen. Manager

Name: \_\_\_\_\_ Mail: \_\_\_\_\_ Telephone: \_\_\_\_\_

## Management representative

Name: \_\_\_\_\_ Mail: \_\_\_\_\_ Telephone: \_\_\_\_\_

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

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**Products / Product groups / Services**

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**Main production process**

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**External consultation for Management system by:**

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

## Existing or previous Certifications

standard:	Certificate valid until:	Certification body:	Last audit day of initial / or Re-Cert

**Individual comments** (e.g. number of construction sites, external projects)

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Audit language: \_\_\_\_\_

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

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

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

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

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

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

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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> <i>(important for IATF 16949 / VDA 6.X, ISO 13485)</i>			
<b>Extended workbench(es)</b>  <i>(important for IATF 16949 / VDA 6.X, ISO 13485)</i>	Address:  Process(e):	Address:  Process(e):	Address:  Process(e):
<b>Supporting functions , that are executed in remote locations</b> <i>(Example: Sales, Design)</i>  <i>(important for IATF 16949 / VDA 6.X, ISO 13485)</i>	Address:  Process(e):  If relevant, number of supporting employees:  _____	Address:  Process(e):  If relevant, number of supporting employees:  _____	Address:  Process(e):  If relevant, number of supporting employees:  _____

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## 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, e.g. offices)</p>			

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## Only for norm ISO 50001

For more than 3 locations use add. sheet	Main location / Headquarter	Location 2:	Location 3:
<b>Amount of energy consumption</b>	<input type="checkbox"/> < 5.500 MWh <input type="checkbox"/> 5.500 – 55.500 MWh <input type="checkbox"/> 55.500 – 555.500 MWh <input type="checkbox"/> > 555.500 MWh	<input type="checkbox"/> < 5.500 MWh <input type="checkbox"/> 5.500 – 55.500 MWh <input type="checkbox"/> 55.500 – 555.500 MWh <input type="checkbox"/> > 555.500 MWh	<input type="checkbox"/> < 5.500 MWh <input type="checkbox"/> 5.500 – 55.500 MWh <input type="checkbox"/> 55.500 – 555.500 MWh <input type="checkbox"/> > 555.500 MWh
<b>Types of energy (in MWh)</b> Only external energy sources are relevant; Steam, for example, if it 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 obtained externally, these energy types are / are to be ticked / 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"/> Compr. air <input type="checkbox"/> Fuels <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"/> Compr. air <input type="checkbox"/> Fuels <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"/> Compr. air <input type="checkbox"/> Fuels <input type="checkbox"/>
<b>Description of major energy consumers (with a share of total consumption &gt; 5%)</b> (e.g. electric melting furnace, cupola furnace, injection moulding machines, drying furnace, thermal afterburners, compressed air compressors, heating systems, cooling/ventilation systems, ...)	1. 2. 3. 4. 5. 6. 7. 8. 9. 10.	1. 2. 3. 4. 5. 6. 7. 8. 9. 10.	1. 2. 3. 4. 5. 6. 7. 8. 9. 10.
<b>EnMS relevant no. of employees</b> 1. TOP Management, ENMR and Members of energy-team; 2. Other persons responsible for the effectiveness of the EnMS / Managers with influence on energy consumption; (eg area / department manager, plant manager/Maintenance). (No multiple counting for employees with several relevant functions)	No. for:  1. 2.	No. for:  1. 2.	No. for:  1. 2.

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## Only for standard DIN EN ISO 45001 / 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>Additional factors on location with influence on audit time</b>			
<b>Self-assessment of risk relevance:</b> <b>High (RK1)</b> <i>(where failure to control the risk may endanger life or have serious consequences. Injury or illness)</i> <b>Medium (RK2)</b> <i>(where the lack of risk control can lead to injury or illness)</i> <b>Low (RK3)</b> <i>(if the failure to control the risk can lead to minor injuries or illnesses)</i>			

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## 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.

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### 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:  
  $\leq 10\%$                         $11\% \leq x \leq 30\%$                         $> 30\%$
- Product inspection process is documented in the companies procedures  
 **yes**                                       **no**



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## 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>

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

**Critical supplier:**

<b>critical supplier</b>	<b>location</b>	<b>process / components</b>

**Language:**

German:

English: