

**Audit Report**  
**No.: 21123154\_004 (TRPS)**  
**30790007\_001 (TRNA)**



TÜV Rheinland  
 Berlin Brandenburg

**Att. 1**  
**Evaluation of QMS requirements – MHLW Ordinance No. 169**

Quality management system requirement		Deviation Report(s) No.	Evaluation (See legend below, evaluation during audit)	Evaluation (See legend below, evaluation of corrective action)
<b>Section 2 Quality management system</b>				
5 (4.1)	Requirements regarding quality management system	No. 2	3 mi	1
6 (4.2.1)	Documentation of quality management system		1 →	
7 (4.2.2)	Quality manual		1 →	
8 (4.2.3)	Document control		1 →	
9 (4.2.4)	Record control		1 →	
<b>Section 3 Management responsibility</b>				
10 (5.1)	Involvement of management		1 →	
11 (5.2)	Customer focus		1 →	
12 (5.3)	Quality policy		1 →	
13 (5.4.1)	Quality objectives		1 →	
14 (5.4.2)	Quality management system planning		1 →	
15 (5.5.1)	Responsibility and authority		1 →	
16 (5.5.2)	Engineering Manager / Responsible Technician		1 →	
17 (5.5.3)	Internal communication		1 →	
18 (5.6.1)	Management review		1 →	
19 (5.6.2)	Management review input		1 →	
20 (5.6.3)	Management review output		1 →	
<b>Section 4 Resource Management</b>				
21 (6.1)	Provision of resources		1 →	
22 (6.2.1)	Human resources		1 →	
23 (6.2.2)	Training, etc.		2 →	
24 (6.3)	Infrastructure		1 →	
25 (6.4)	Work environment		1 →	
<b>Section 5 Product Realization</b>				
26 (7.1)	Planning of product realization		1 →	
27 (7.2.1)	Determination of requirements related to the product		1 →	
28 (7.2.2)	Review of requirements related to the product		1 →	
29 (7.2.3)	Customer communication		1 →	
30 (7.3.1)	Design and development planning		1 →	
31 (7.3.2)	Design and development inputs		1 →	
32 (7.3.3)	Design and development outputs		1 →	
33 (7.3.4)	Design and development review		1 →	
34 (7.3.5)	Design and development verification		1 →	
35 (7.3.6)	Design and development validation		1 →	
36 (7.3.7)	Control of design and development changes		1 →	
37 (7.4.1)	Purchasing process	No 3, 4	3 mi	1
38 (7.4.2)	Purchasing information		2 →	
39 (7.4.3)	Verification of purchased product		1 →	

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Quality management system requirement		Deviation Report(s) No.	Evaluation (See legend below.)	Evaluation (See legend below.)
40 (7.5.1.1)	Production and service provision		1 →	
41 (7.5.1.2.1)	Cleanliness of product control		1 →	
42 (7.5.1.2.2)	Installation activities		1 →	
43 (7.5.1.2.3)	Servicing activities		Na	Na
44 (7.5.1.3)	Production control of sterile product		Na	Na
45 (7.5.2.1)	Validation of processes for production, etc.		Na	Na
46 (7.5.2.2)	Validation of sterilization process, etc.		Na	Na
47 (7.5.3.1)	Identification		1 →	
48 (7.5.3.2.1)	Establishment of traceability		1 →	
49 (7.5.3.2.2)	Establishment of traceability for specified product		1 →	
50 (7.5.3.3)	Status identification of product		1 →	
51 (7.5.4)	Customer property		na	na
52 (7.5.5)	Preservation of product		1 →	
53 (7.6)	Control of equipment and tools	No. 1	3 mi	1
<b>Section 6 Measurement, Analysis and Improvement</b>				
54 (8.1)	Measurement, Analysis and Improvement		1 →	
55 (8.2.1)	Feedback from customer		1 →	
56 (8.2.2)	Internal audit		1 →	
57 (8.2.3)	Monitoring and measurement of processes		1 →	
58 (8.2.4.1)	Monitoring and measurement of product		1 →	
59 (8.2.4.2)	Monitoring and measurement of specified product		1 →	
60 (8.3)	Control of nonconforming product		1 →	
61 (8.4)	Analysis of data		1 →	
62 (8.5.1)	Improvement		1 →	
63 (8.5.2)	Corrective action		1 →	
64 (8.5.3)	Preventive action		1 →	
<b>Legend:</b> 1 : Conformity with QMS requirement (nearly =Rank A) 2 : Conformity with finding, still acceptable (nearly =Rank B) 3 mi=3 minor : Minor or medium non-conformity with QMS requirement (nearly =Rank C) 3 ma= 3 major : Major non-conformity with QMS requirement (nearly =Rank D) N.A. : Exclusive/not applicable				
QMS conformity evaluation result of (licensed) manufacturer (See legend below)		QMS on-site audit result		QMS conformity evaluation result
		<input checked="" type="checkbox"/> Conformity <input type="checkbox"/> Near-conformity <input type="checkbox"/> Improvement required <input type="checkbox"/> Nonconformity		<input checked="" type="checkbox"/> Conformity <input type="checkbox"/> Nonconformity
<b>Legend:</b> Conformity: 1 and/or 2 only Near-conformity: 1 and/or 2 and/or 3 minor=<1/5 of applicable requirements numbers AND no 3 major Improvement required: Total number of 3 minor>1/5 of applicable requirements numbers AND no 3 major Nonconformity: Any cases not covered in the above (Ex. 3 major is included.)				