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**1 Purpose**

This SOP describes the consistent procedure to ensure the forwarding and processing of complaints, appeals and disputes against MEDCERT.

**2 Scope**

This procedure is applied to all appeals, complaints, disputes (summarized under “complaints” in the following), which are directed against MEDCERT. Any conflict of interest indicated by the customer will be handled as a complaint.

**3 Responsibilities**

The responsibilities for the individual procedure steps are defined in the column “V” of the flow chart.

The Certification Body is responsible for complaints regarding certification processes (CB in column “V”). The General Manager is responsible for all other complaints (GF in column “V”). In any case it has to be ensured that the persons engaged in the appeals-handling process are different from those who carried out the audits and made the certification decisions.

**4 Description**

**4.1 Text Version**

**4.1.1 Complaints, Appeals and Disputes**

It is pointed out to the complainant, that complaints are only subject to the procedure if they are presented in written form. Submission, investigation and decision on appeals will not result in any discriminatory actions against the appellant.

If necessary or possible, the Certification Body will provide the complainant with progress reports.

**4.1.2 Mediation Procedure**

**Mediation committee ▶**

The mediation committee is composed of a chairman and selected members, depending on the type of the complaint.

A member is replaced by another person for the duration of the processing of the complaint, in the case that a joint interest of the complainant and a member of the mediation committee do exist.

Members of MEDCERT are not allowed to be members of the mediation committee, nor are they allowed to have any economic interest in MEDCERT.

All work in the mediation committee is voluntary work. MEDCERT pays for all expenses connected with the work of the mediation committee.

Members of the mediation committee are committed to handle all knowledge, which they become aware of as a member of the mediation committee confidential towards third parties.

It is the duty of the mediation committee to hear the involved parties and to take all available information into consideration.

**Decisions ▶**

For all decisions which are made in this procedure, the regulatory requirements and rules of the designation / accreditation which are applied to MEDCERT need to be considered. See also Flow Chart.

**4.2 Flow Chart**

See page 3 to 5

			MDOK	V
Start				
Receipt of Complaint			Complaints, objections and disputes require the written submission by the complainant	entire MEDCERT
Receipt of complaint in written form?	<b>no</b>	Request for written complaint		entire MEDCERT
	<b>yes</b>			
Complaint against customer?	<b>yes</b>	SOP 13 03		entire MEDCERT
	<b>no</b>			
Complaint regarding certification process?	<b>no</b>			Entire MEDCERT
	<b>yes</b>			
Transmission to and evaluation by CB		Transmission to and evaluation by GF		CB/GF
Contact to complainant				CB/GF
Information sufficient for evaluation?	<b>no</b>	<b>yes</b>	Confirmation receipt of complaint to customer	CB/GF
			investigation of complaint	CB/GF

						<b>MDOK</b>	<b>V</b>
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Complaint accepted?	<b>no</b>	Information to complainant					CB/GF
	<b>yes</b>						
Entry in		Verification and measure:					CB/GF
• MCDB "CAPA"		• kind and nature of conflict					
• DMS		• If independence of staff affected					
		• if impartiality of personell affected					
Conflict of interest ?	<b>yes</b>	Identification / review of interest of conflict	internal clarification possible?	<b>no</b>	SOP 01 02	CB/GF	
	<b>no</b>						
		<b>yes</b>					
Clarification possible?	<b>no</b>	Subprocedure: mediation procedure					CB/GF
	<b>yes</b>						
Decision about complaint		<ul style="list-style-type: none"> <li>The decision shall be made by, or reviewed and approved by, individual(s) not previously involved in the subject of the appeal.</li> <li>Determination together with the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public.</li> </ul>					CB/GF
Entry in		Information of complainant regarding outcome					CB/GF
• MCDB "CAPA"							
• DMS							
Improvement of QA system	<b>yes</b>	Weaknesses of QA-system detected?				SOP 14 01	QMB
		<b>no</b>					
Implementation of CAPA action	<b>yes</b>	Further weaknesses detected?	<b>no</b>			SOP 14 01	CB/GF
End							

	<b>MDOK</b>	<b>V</b>
<p>Subprocedure: Mediation Procedure</p>		
<p>Formation of the Mediation Committee</p>		CB/GF
<p>Information of complainant about his rights in the mediation process</p>		MEDIATION COMMITTEE
<p>Hearing of <b>yes</b> witnesses/experts necessary?  <b>no</b></p>	<p>Selection of witnesses/experts</p>	MEDIATION COMMITTEE
<p>Adjustment and fixing of date with complainant</p>		MEDIATION COMMITTEE
<p>Meeting of Mediation Committee</p>		MEDIATION COMMITTEE
<p>Assessment of issue and decision making</p>	<p>- Vote with bare majority - In case of dissenting opinions those have to be documented</p>	MEDIATION COMMITTEE
<p>Report to complainant and MEDCERT</p>	<p>The report -is to be signed by all members of the mediation committee -regulates all cost issues</p>	MEDIATION COMMITTEE
<p>End Subprocedure</p>		

**5 Documentation**

The documentation is to be applied according to the flow chart (4.2).

**6 Additional Applicable Documents**

The additional applicable documents are defined in the column **MDOK** of the flowchart.

Terms and Abbreviations not defined in the procedure itself are listed in H00-3e “Terms and Abbreviations”.

<b>QM Modification Log</b>	
MSH 2019.06.04	Correction of the first sentence in section 6 (a part was lost)
MSH 2019.06.05	This is the copy for publication without marking of changes.