

## **Table of Content**

- 1 Purpose
- 2 Scope
- 3 Responsibilities
- 4 Description
  - 4.1 Text Version
    - 4.1.1 Complaints, appeals and disputes
    - 4.1.2 Mediation procedure
  - 4.2 Flow Chart
- 5 Documentation
- 6 Additional Applicable Documents

## 1 Purpose

This SOP describes the process to ensure the receiving, evaluation, validation, investigation and decision of complaints, appeals and disputes against DNV MEDCERT.

## 2 Scope

This procedure is applicable for all appeals, complaints and disputes (summarized under “complaints” in the following), which are addresses to DNV MEDCERT and to customers certified by DNV MEDCERT. Any conflict of interest indicated by any person or company will be handled as a complaint and according to this procedure.

## 3 Responsibilities

The responsibilities for the individual procedure steps are defined in the column „**RESPONSIBILITIES**“ of the flow chart (see 4.2).

The Chief Certification is responsible for complaints related to auditor(s), experts, subcontractors and the auditing or certification processes (CC in column “**RESPONSIBILITIES**”). The Managing Director is responsible for all other complaints (MD in column “**RESPONSIBILITIES**”), mainly related to commercial issues. In any case it will be ensured that the persons engaged in the complaint-processing process are not previously directly involved in the subject of the complaint.

## 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.

#### **Whistleblower complaints about MDSAP customers ▶**

Complaints/information about MDSAP audited/certified customers indicating public health threat or serious doubt in the safety and effectiveness of medical devices must be forwarded to the recognizing Regulatory Authorities.

#### 4.1.2 Mediation procedure

##### **Mediation committee ▶**

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

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

Employees of DNV MEDCERT are neither allowed to be members of the mediation committee, nor are people accepted as members of the mediation committee, if they have any economic interest in DNV MEDCERT.

All work in the mediation committee is done voluntary; DNV MEDCERT pays only for the extra expenses connected with the work of the mediation committee.

Members of the mediation committee are committed to handle all information and documents, which they become aware of as a member of the mediation committee, strictly confidential.

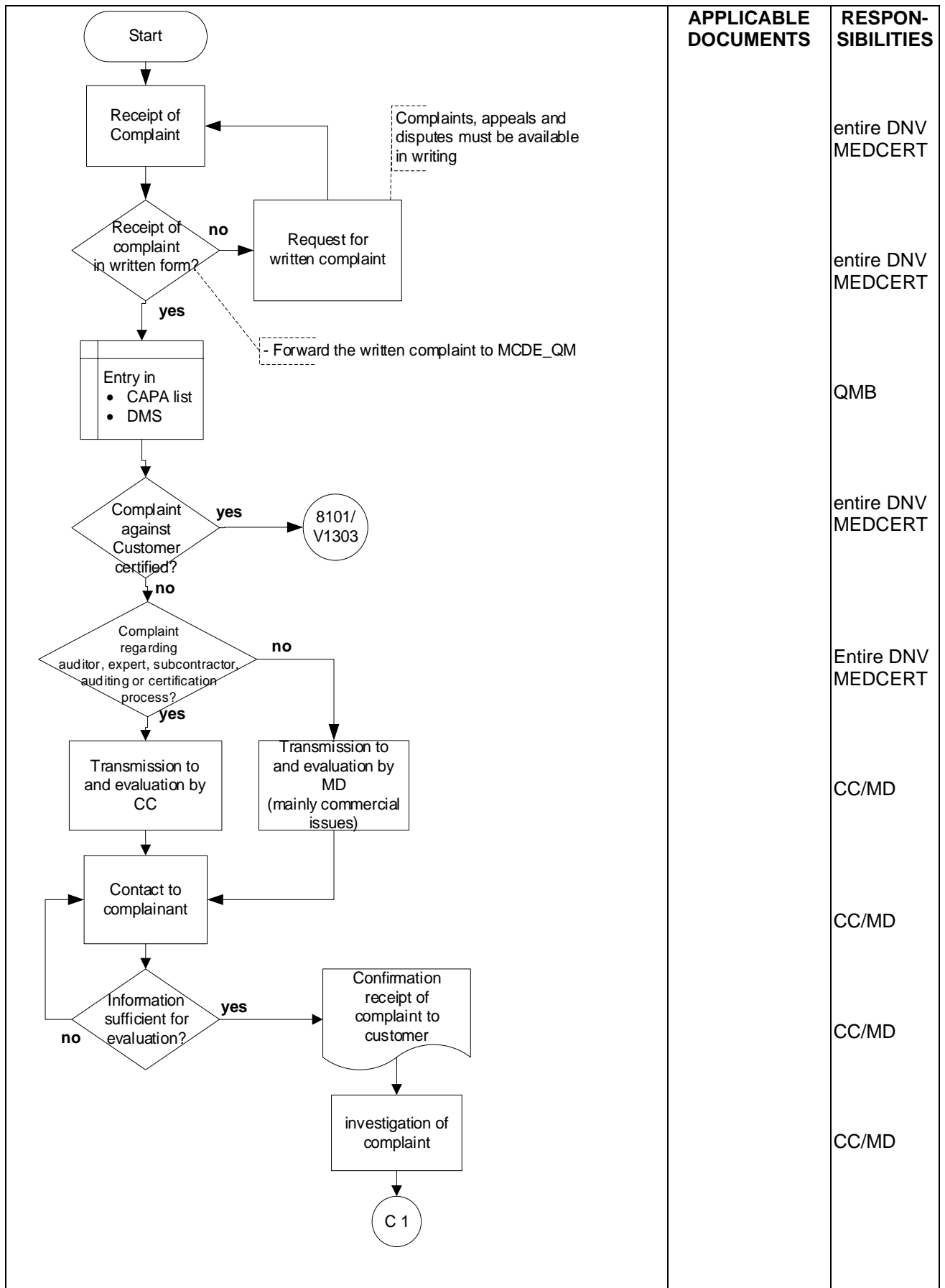
It is the task of the mediation committee to hear and interview the involved parties and to take all available information into consideration for their decision.

**Decisions ▶**

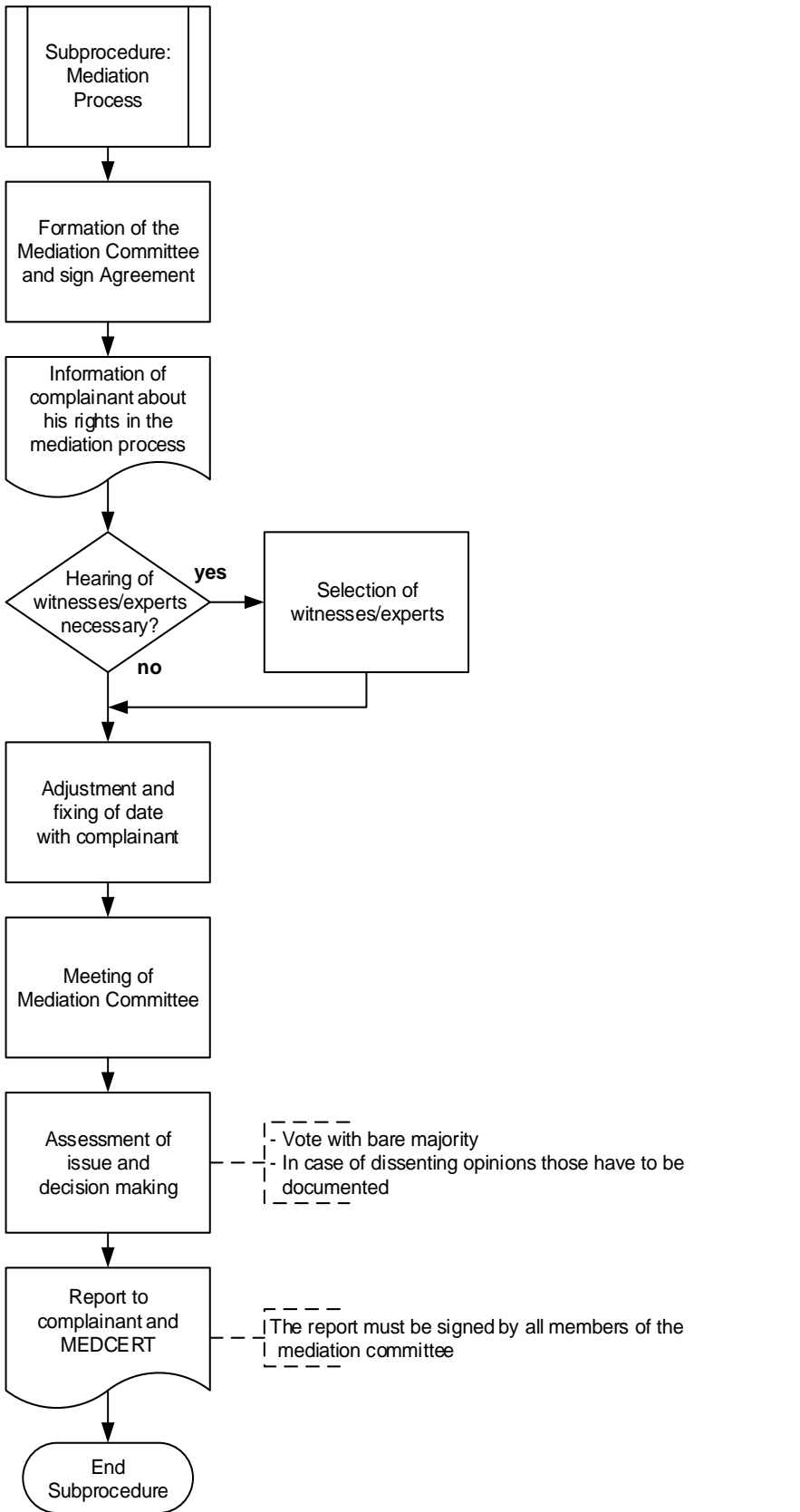
For all decisions which are made, the regulatory and normative requirements and designation / accreditation rules, which are applicable for DNV MEDCERT, must to be considered. See also Flow Chart.

**4.2 Flow Chart**

See following pages



	APPLICABLE DOCUMENTS	RESPON-SIBILITIES
<pre> graph TD     C1((C 1)) --&gt; D1{Complaint accepted?}     D1 -- no --&gt; I1[Information to complainant]     I1 -.-&gt; A1[Also inform MDCE_QM]     D1 -- yes --&gt; U1[Update entry • CAPA list • DMS]     U1 --&gt; D2{Conflict of interest?}     D2 -- yes --&gt; I2[Identification / review of interest of conflict]     I2 --&gt; D3{internal clarification possible?}     D3 -- no --&gt; C1_2((5501/V0102))     D3 -- yes --&gt; D4{Clarification possible?}     D4 -- no --&gt; S1[Subprocedure: mediation process]     D4 -- yes --&gt; D5{Decision about complaint}     S1 --&gt; D5     D5 -.-&gt; A2[• The decision shall be made by, or reviewed and approved by, individual(s) not previously directly involved in the subject of the appeal. • Determination together with the complainant, whether and, if so to what extent, the subject of the complaint and its resolution shall be made public. • Take into account the results of previous similar complaints • Also inform MCDE_QM]     D5 --&gt; U2[Update entry • CAPA list • DMS]     U2 --&gt; I3[Information of complainant regarding outcome]     I3 --&gt; D6{Weaknesses of QM system detected?}     D6 -- yes --&gt; I4[Improvement of QM system]     D6 -- no --&gt; D7{Further weaknesses detected?}     D7 -- yes --&gt; I5[Implementation of CAPA action]     D7 -- no --&gt; End((End))     I4 --&gt; End     I5 --&gt; End                     </pre>	<p>8501</p> <p>8501</p>	<p>CC/MD</p> <p>QMB</p> <p>CC/MD</p> <p>CC/MD</p> <p>CC/MD</p> <p>CC/MD</p> <p>QMB</p> <p>CC/MD</p>

	APPLICABLE DOCUMENTS	RESPONSIBILITIES
 <pre> graph TD     A[Subprocedure: Mediation Process] --&gt; B[Formation of the Mediation Committee and sign Agreement]     B --&gt; C[Information of complainant about his rights in the mediation process]     C --&gt; D{Hearing of witnesses/experts necessary?}     D -- yes --&gt; E[Selection of witnesses/experts]     E --&gt; D     D -- no --&gt; F[Adjustment and fixing of date with complainant]     F --&gt; G[Meeting of Mediation Committee]     G --&gt; H[Assessment of issue and decision making]     H --&gt; I[Report to complainant and MEDCERT]     I --&gt; J([End Subprocedure])     </pre>	<p>740112</p>	<p>CC/MD</p> <p>MEDIATION COMMITTEE</p> <p>MEDIATION COMMITTEE</p> <p>MEDIATION COMMITTEE</p> <p>MEDIATION COMMITTEE</p> <p>MEDIATION COMMITTEE</p> <p>MEDIATION COMMITTEE</p> <p>MEDIATION COMMITTEE</p>

**5 Documentation**

This documentation is done according to the flow chart (see 4.2).

**6 Additional Applicable Documents**

No further additional applicable documents.

Terms and Abbreviations not defined in the procedure itself are listed in Manual 41-3 Terms and Abbreviations.