

Subject of the Agreement: Confidentiality and impartiality principles, working principles, and mutual relationships with Malta Conformity Assessment Ltd. (will be referred as MCA in this document from thereon) and the rights and responsibilities of the committees and the chairman of the committee, members, and reserve members of the committees thereon, as established in accordance with the management system implemented by MCA.

Parties: Chairman of the committee, Members, and Reserve Members of the Appeal Committee, Conservation of Impartiality Committee, and Certification Committee (shall be referred to as the committee members from thereon).

LIABILITIES AND POWERS OF THE COMMITTEE MEMBERS

1. The committee members shall carry out all the activities in accordance with the requirements of the related accreditation standards and regulations and the procedures of MCA.
2. The committee members shall keep any and all information and documents they have obtained related with MCA, clients of MCA, and the persons and entities related with MCA confidential, and shall not share these with third parties except to the authorities responsible for notified bodies, competent authorities for medical devices and in vitro diagnostic medical devices in the Member States, the Commission or required by law in writing or verbally. The committee members shall follow the confidentiality practices documented in PR.11 Confidentiality Impartiality Objectivity Conflict Of Interest And Risk Analysis Procedure, for medical devices services PR.MED.37 Medical Devices Procedure for Special Confidentiality Management Rules, and for in vitro medical devices services PR.IVD.37 In Vitro Diagnostic Medical Devices Procedure for Special Confidentiality Management Rules and will treat the confidential information as documented in these documents.
3. The committee members may not assign their assignments and powers within the committee to third persons or groups, in part or in whole.
4. All the members assigned in the committees to be created by MCA shall act independently on any subject, which they will make a decision on, and shall not decide with the effect and direction of other persons and/or entities.
5. The committee members shall notify MCA Quality Manager of any situation that might affect their impartiality and independency about the decisions they will make, and shall withdraw from their assignments in the committee related with the subject.
6. The committee members shall avoid any non-objective, sided, and intolerable behaviors related with the activities they have been carrying out, which might affect the companies adversely, and shall always maintain an objective and independent approach.
7. The committee members may request any kind of information and documentation from MCA, discuss with persons related with the subject, and consult to their comments, in order to get detailed information on any subject.
8. The committee members shall attend to meetings held in planned intervals and/or in extraordinary cases.
9. The committee members shall inform MCA when they will not attend to a planned or extraordinary meeting at least 7 days before the date of the meeting.
10. The committee members shall inform MCA about any changes of work and assignment, their qualifications and their education during their membership in 15 days.
11. In case that any committee member requests an extraordinary meeting, the concerning member shall notify Quality Manager of the case, and the committee meetings are held with the organization of MCA.
12. The personal is entitled to be appointed to be membership of the committee following the signing of this agreement. The committee member is considered appointed when it is recorded in the FR.47 Committee List. Memberships of committee members who fail to attend three consecutive meetings shall be terminated. Memberships of committee members wishing to terminate their membership in writing shall be terminated.
13. In case that any information or suspicion occurs about the decisions made by the committee are not implemented by the employees of MCA, the Chairman or any member of the committee shall see the General Manager and give information for the correction of the situation.
14. If no conclusion is arrived from the discussion with the General Manager, the committee shall directly see the accreditation institute or the authority responsible for the notified body and notify them.
15. The Committee member shall commit to obey following declarations and inform MCA about the existing of following issues immediately and shall refuse the task when such conflict exists.
 - There is no situation which can cause risks according to the principles of this agreement which I have signed during the assignment period in MCA.
 - I have no close relationship (kindship, friendship, share/partnership, financial investment (including directly holding stocks), employment, etc.) that endanger my impartiality, independence, objectivity with the company which I have been assigned for and stated above.

- I am not the designer, manufacturer, supplier, installer, purchaser and/or owner, maintainer, consultant or authorized representative of the manufacturer, the subject devices or companies belonging to the same group with the manufacturer that I participate in the committee assessments. I declare that I have not been involved in any activity to the above-mentioned issues in the last three years.
- I am not engaged in any activity that may conflict with my independence of judgement or integrity in relation to meeting agenda for which I am designated.
- I did not work in the manufacturer or companies belonging the same group of companies with the manufacturer and which will be assessed in the meeting. I did not involve in any activity which will be a valid input to the subject assessment such as being involved with a clinical investigation, scientific study, clinical evaluation, test etc. for the same manufacturer or the sponsor of the subject manufacturer.
- I will obey all the rules stated in the MCA procedures.
- I will follow the confidentiality rules defined in PR.11 Confidentiality Impartiality Objectivity Conflict of Interest and Risk Analysis Procedure and in this agreement during and after the performance of my tasks.
- I have accepted the task and I will perform my task fairly, depending on the objective evidences and under no influence.
- I declare that I will not accept the assignment with related Committee Task Assignment Form and/or I will not vote if I have engaged in any activity that may conflict with my independence or impartiality regarding the agenda of the meeting to which I have been assigned.
- I declare that I will immediately inform MCA if any of my information which can create a conflict of interest.

LIABILITIES AND POWERS OF MCA

1. The top management and employees of MCA are liable to comply with the decisions of the Committee with all its units, and provide implementation of the decisions made after the committee meeting.
2. The top management and employees of MCA may not create pressure in any way for any decisions taken or to be taken by the members of the committee while fulfilling their assignments.
3. MCA is liable to provide meetings of the Committees at required place and time and appropriate working conditions for them.
4. MCA is liable to make available any information and documents requested by the members to committee members and provide them to see any person, in order to make it possible for the committees to work efficiently and make objective assessments.
5. In case that any situation occurs, which might affect the impartiality of the Committee members on any subject, MCA is liable to prevent such members from taking place in discussions and decision-making processes about that subject.
6. Conservation of Impartiality Committee shall meet at least once a year, with the call of General Manager of MCA. In extraordinary cases, the General Manager may request an additional meeting. In case that any permanent member does not attend to a meeting, the reserve member is invited.
7. When necessary, the requested MCA personnel, or any person who will be consulted about the subject may attend the meeting, however they shall not have any right to state their decision at voting.
8. Membership of any committee member who has not attended three consecutive meetings shall be terminated without the requirement of any warning.

OTHER

1. The related member will be assigned for the following Committee with this agreement;
 - ☐ Appeal Committee
 - ☐ Conservation of Impartiality Committee
 - ☐ Certification Committee
2. In case of any disputes, the courts of Malta shall be authorized.
3. This agreement which consists of 26 clauses shall be effective when it is signed mutually.

I accept and undertake to comply with the above clauses.

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Committee Member	MCA General Manager
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**COMMITTEE MEMBERS
CONFIDENTIALITY AND IMPARTIALITY AGREEMENT**

Date :
Name and Surname :
Signature :

Date :
Name and Surname :
Signature :