

This service agreement is used to set up the rules between external experts and Malta Conformity Assessment Ltd.

Following table shows the interchangeability of titles and shall mean the same.

Lead Auditor	Head Of Audit Team
Auditor	QMS Auditor
Technical Expert	Product Assessor

LIABILITIES OF THE LEAD AUDITOR/AUDITOR/ TECHNICAL EXPERT

1. The Lead Auditor / Auditor / Technical Expert shall not disclose any information they have learned either about Malta Conformity Assessment Ltd. (will be referred as MCA in this document) or the company, which requests to be certified under any circumstances and for any reason except to the authorities responsible for notified bodies, competent authorities for medical devices in the Member States, the Commission, Accreditation Institutes or required by law. In case that it is proven that such information or documents were disclosed, the Lead Auditor / Auditor / Technical Expert shall compensate all the damages incurred by MCA and the company which requests to be certified.
2. The works that constitute the subject of this agreement shall be carried out by the Lead Auditor / Auditor / Technical Expert in accordance with the concerning legislation, standards, regulations, and MCA procedures.
3. The Lead Auditor / Auditor / Technical Expert shall not damage both MCA and the employees and properties of the company which requests to be certified, and shall burden the financial and penal consequences of any damages it might cause.
4. The Lead Auditor / Auditor / Technical Expert may not assign the work to third persons or companies either in whole or in parts.
5. In case that the Lead Auditor / Auditor / Technical Expert cannot complete, or it appears like that they will not complete the work within due time, or do not carry out the work as it was requested, and it is understood that they will not carry out despite the warning, they shall burden other legal and financial liabilities with the termination of this agreement.
6. The Lead Auditors / Auditors / Technical Experts undertake to notify MCA of any finished or ongoing business relationship within last 3 years before undertaking any assignment. They shall obey with the principles stated in PR.11 Confidentiality, Impartiality, Objectivity, Conflict of Interest and Risk Analysis Procedure and FR.10 Confidentiality and Impartiality Commitment.
7. The Lead Auditor / Auditor / Technical Expert undertake to avoid any non-objective comments and assessments, and be objective and independent during the audit.
8. The Lead Auditor / Auditor / Technical Expert shall not demand money, gift, or any interest from the audited company or its employees. In case that these are offered or granted, they will reject these, and then inform MCA.
9. They undertake to inform any change about the qualification and education status to MCA during the agreement period.
10. The Lead Auditor / Auditor / Technical Expert undertake to attend to trainings invited by MCA during the agreement period.
11. In case that the Lead Auditor / Auditor / Technical Expert is in a situation that might damage their confidentiality, security, or impartiality, and in case of any damages they might give either to MCA or to the companies under certification, they shall be liable to cover any losses that might arise.

12. Audit team should make sure that all occupational safety and health precautions are taken on site. In case of a situation which can endanger occupational safety and health, the audit team should ask for correcting this situation. If safe working environment cannot be provided, the audit team should not be performed or quit the tasks.
13. By signing this agreement, the person declares that he/she understands that following are types of conflict of interests and will result on restrictions to perform tasks and shall immediately notify Malta Conformity Assessment Ltd.

Conflict Type	Resolution Period
Previously employed by a manufacturer or supplier, authorized representatives of a manufacturer	3 years
having a close relationship with above mentioned companies such as kinship.	Permanent
Commercial Competitors of previously employed manufacturer	3 years
Consultation for the manufacturer or its suppliers, authorized representatives,	3 years
Provided Training (only client specific training activities)	1 year
Received Training (only client specific training activities)	1 year
Clinical researchers (participated in the clinical trials for a product of a manufacturer)	Permanent
Working/consultancy experience for a supplier company a manufacturer	3 Years

LIABILITIES OF MCA

1. MCA shall pay ...* per day to the Lead Auditor/Auditor/Technical expert for audits undergone at the client's premises, after the delivery of the audit report. The payment shall be done after completion of the services. No payment is made for audits to which the Auditor and the Lead auditor attend for the purpose of training and monitoring.
2. Any damages that might be caused to the equipment and third parties during the auditing activities carried out by the Lead Auditor / Auditor / Technical expert to be assigned by MCA for any audit shall be covered by the professional liability insurance covered by MCA.
3. Any risks and losses that might be incurred by the audit team while going to and returning back from the place of audit shall be covered from the social security of the members in the audit team.
4. The damages of any members who are not subject to any social security organization shall be covered from the social security to be valid for the days of assignment by MCA and/or optionally, provided that their situation is notified to MCA in writing.
5. MCA is liable to give any audit documents related with the works it will have done within due time.
6. MCA is liable to protect confidentiality of all the documents and information related with the Lead Auditor / Auditor / Technical Expert.

THE AUTHORIZED COURT AND EXECUTION OFFICE

1. For any disputes that might arise out of this agreement, Malta Courts and Execution Offices shall be authorized.

This agreement by and between MCA and the Lead Auditor / Auditor / Technical Expert was signed on .../.../20.... with the mutual consent of the parties, shall come into force on the date of signing, and shall be valid. This agreement shall be repealed by the written request of either party.

MALTA
CONFORMITY ASSESSMENT LTD.

Lead Auditor / Auditor / Technical Expert

Name and Surname:

Name and Surname:

Signature:

Signature:

* For the employees of contact offices this amount will be paid to the contact office.