EXTERNAL HEAD OF AUDIT TEAM / SITE AUDITOR / PRODUCT REVIEWER / CLINICAL SPECIALIST SERVICE AGREEMENT

This service agreement is used to set up the rules between external experts and Malta Conformity Assessment Ltd (will be referred as MCA in this document).

LIABILITIES OF THE HEAD OF AUDIT TEAM / SITE AUDITOR / PRODUCT REVIEWER / CLINICAL SPECIALIST

1. The Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist shall not disclose any information they have learned either about Malta Conformity Assessment Ltd. 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 or required by law. In case that it is proven that such information or documents were disclosed, the Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist in accordance with the concerning legislation, standards, regulations, and MCA procedures.
3. The Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist may not assign the work to third persons or companies either in whole or in parts.
5. In case that the Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist undertake to avoid any non-objective comments and assessments, and be objective and independent during the audit.
8. The Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist undertake to attend to trainings invited by MCA during the agreement period.
11. In case that the Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 manufacturer, designer, supplier, installer, purchaser, maintainer,	a) 3 years for effected companies and companies belonging to the same group of companies, starting from stopping the above involvements

and authorized representative of medical devices and/or in vitro diagnostic medical devices • Being the designer, manufacturer, supplier, installer, purchaser, maintainer, or authorized representative of devices. (Including representing parties engaging with these activities) • Being involved in the design, manufacture or construction, marketing, installation and use, or maintenance of the devices (Including representing parties engaging with these activities)	b) Permanent ban for experienced single devices (cannot assess the devices that he/she provided inputs for the assessment)
Provided Consultancy to the Devices	a) 3 years ban for the affected companies and companies belonging to the same group of companies, starting from the last day of the consultancy activity. b) 3 years ban for commercial competitors, authorized representatives, and suppliers (filtered according to experienced devices) of the manufacturer from the last day of the consultancy activity. c) If filtering or identifying commercial competitors is not possible according to the above item b) blocking a part of/ or complete MDA/MDN/IVR code for 3 years starting from the last day of the consultancy activity. When there is a blockage for MDA/MDN/IVR code, the person shall also not participate in any review or audit for MDS/MDT/IVS/IVT codes defined in connection with blocked MDA/MDN/IVR codes.
Currently employed by manufacturer, designer, supplier, installer, purchaser, maintainer, and authorized representative of medical devices and/or in vitro diagnostic medical devices	a) Permanent ban for the affected companies and companies belonging to the same group of companies b) Permanent ban for commercial competitors, authorized representatives, and suppliers of the manufacturer. c) If identifying commercial competitors is not possible according to the above item b), blocking a part of/ or complete MDA/MDN/IVR code. When there is a blockage for MDA/MDN/IVR code, the person shall also not participate in any review or audit for MDS/MDT/IVS/IVT codes defined in connection with blocked MDA/MDN/IVR codes.
Being the Designer of a Device (Holding design rights)	Permanent ban for experienced single devices until the ownership ends
Participated in the clinical trials for a device of a manufacturer (clinical researchers)	Permanent ban for affected single devices
Having a close relationship, kinship, financial interest, and direct investment (including company stocks) in companies; companies belonging to the same group of companies; suppliers and commercial competitors of the subject companies that; - are manufacturer, designer, supplier, installer, purchaser, maintainer, and authorized representative of medical devices and/or in vitro	Until the financial interest ends. Permanent ban for kinship& close relationship.

diagnostic medical devices (Including representing parties engaging with these activities) - involve in the design, manufacture or construction, marketing, installation, and use, or maintenance of the devices (Including representing parties engaging with these activities)	
Provide a testing report which is not outdated and which is valid for a certified device	Ban for the affected each single device only until the test report is outdated. (only for the discipline where the testing report is relevant)

LIABILITIES OF MCA

1. MCA shall pay * Please choose. to the Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist

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 Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist 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.	**Head of Audit Team / Site Auditor / Product Reviewer / Clinical Specialist**
Name and Surname:	Name and Surname:
Signature:	Signature:

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