

CONFIDENTIALITY AND IMPARTIALITY COMMITMENT

I commit that,

Do not have any close relations (kinship, friendship, share/partnership, financial investment (including directly holding stocks), employment etc.), which may put endanger my impartiality with the customer, whose conformity assessment activities I will perform. I shall immediately notify Malta Conformity Assessment Ltd. (will be referred as MCA in this document) case of existence of such relations,

I have not been engaged with the client that I have been appointed to within the last 3 years for medical device and/or in vitro diagnostic medical device conformity assessment activities, did not provide consultancy, special training to the customer or internal auditing services, and have not worked in an organization, providing such services. In case of similar facts, I shall not accept the assignment and immediately notify MCA,

Shall perform the conformity assessment activities, based on objective evidence, equitable, impartial, independent and honest; to avoid any behavior, which may damage the reputation and prestige of MCA.

Shall not be in a relationship of interest with any person or organization, not claim anything from the person/organization or its representative, I serve to, in my or anybody's favour. In case of such a proposal, I will refuse it and immediately notify MCA,

Shall pay attention to the confidentiality of all data, information and documents, that belong to MCA and its customers, and not disclose them to third parties except to the authorities responsible for notified bodies, competent authorities for medical devices in the Member States, the Commission or required by law,

I understand all types of information gathered during conformity assessments are classified as confidential,

I will secure and apply professional secrecy on confidential information except in relation to the authorities responsible for notified bodies, competent authorities for medical devices in the Member States, the Commission,

I will 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, for in vitro diagnostic 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,

Shall protect all types of intellectual property rights,

Shall ensure the confidentiality and security of all information and documents, obtained during the performance of conformity assessment services unless these services are completed, not keep them once the conformity assessment process is concluded and delivered to MCA to be saved in its file,

Shall not engage in any activity, which may affect my impartiality and independence within the scope of the conformity assessment I will be performing,

I am not a designer, manufacturer, supplier, installer, purchaser and/or owner, maintainer or consultant of devices which I assess, nor the authorised representative of any of those parties, and I do not represent any parties engaging with these activities,

I am not directly involved with the products, subject to conformity assessment or other products in competition (such as competing trademarks or manufacturers). In such case I shall not accept the assignment and immediately notify MCA,

Additional requirements for employees to work in the medical department under Regulation (EU) 2017/745 and/or Regulation (EU) 2017/746;

-I will not engage in such a close relationship (friendship, etc.) that may jeopardize my impartiality during the conformity assessment activities that I will be assigned. In case of such a situation, I will refuse it and immediately notify MCA,

-I did not provide consultancy, on-site training, internal audit service, technical documentation preparation services to the company, or companies belonging to the same group of companies or its authorized representative, or its commercial competitor and supplier to whom I will be assigned for conformity assessment activities in the last 3 years. In case of such proposal, I will refuse it and immediately notify MCA,

- I have not been involved in the design, production, marketing, installation, maintenance, use or quality management system of the products subject to the conformity assessment that I will be assigned for conformity assessment activities in the last 3 years and I did not represent any parties engaging with these activities.

In case of such a proposal, I will refuse it and immediately notify MCA,

-I did not work in the company which will be audited/assessed or was audited/assessed, and I did not and do not have any commercial connection.

In case of the presence of an activity that will be a valid input to the subject conformity assessment such as being involved with a clinical investigation, scientific study, clinical/performance evaluation, test etc for the same manufacturer or the sponsor of the subject manufacturer, I will refuse it and immediately notify MCA,

-With a valid assignment, I will not offer any service to the manufacturers, commercial competitors, suppliers, authorized representatives of the manufacturers, for the devices under my scope of authorization.

If I plan to do so, first I will inform MCA and request ending employment or removal of authorization for affected codes and devices.

If I plan to participate in any study (clinical research, scientific study, academic study, a clinical/performance evaluation, or test, etc.) that is sponsored and that can be valid as input to assessments, I will inform in advance MCA and act as per its decision,

Shall inform MCA about the changes, which may affect my independence and impartiality in the services I perform,

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Shall provide conformity assessment services to all related parties on an equal basis appropriately to MCA documentation, which is established according to MCA's accreditation, notification and authorization based on national and international standards and regulations,

Shall comply with MCA Code of Ethics and MCA Policies,

Shall perform activities, which I am responsible for, without being affected by commercial, financial, and other forces; not be in any pressure or relation to affect the independence of anybody,

I agree to cover all damages and legal indemnifications, which may arise from the failure to meet this commitment and terms, specified in it.

Name Surname:

Signature:

Date: