

## Medical Devices General Terms

In this text,

- The word “MCA” shall refer to Malta Conformity Assessment Ltd.;
- The word “Agreement” shall refer to “Regulation (EU) 2017/745 Conformity Assessment Agreement” issued by MCA;
- The word “Company” shall refer to the manufacturer that has executed an agreement with MCA.

“Medical Devices General Terms” constitutes an inseparable part of agreements, and MCA is entitled to update this document when it considers necessary. If the “Medical Devices General Terms” is updated and any difference occurs with the provisions of the agreement previously executed, the provisions of this document shall prevail, and the company shall be obliged to comply with the provisions that are replaced. The customers shall be informed whenever this document is amended by publication of the updated version on the website. Medical Devices General Terms shall be available at [www.maltaca.com](http://www.maltaca.com).

The “Medical Devices General Terms” defines the conformity assessment activities based on a quality management system and on assessment of technical documentation regarding to Annex IX of the Regulation (EU) 2017/745 and conformity assessment activities based on product conformity verification - production quality assurance regarding to Annex XI - Part A of the Regulation (EU) 2017/745 and the rules to be observed by the company and MCA hereunder and also contains a summary of the assessment processes.

### 1. ASSESSMENT PROCESS

#### 1.1. Application Review and Agreement Process

**1.1.1.** Applications for product conformity assessment regarding the Regulation (EU) 2017/745 concerning Medical Devices shall be lodged in writing along with an application form. Verbal applications shall not be accepted. The company shall fill in and sign the application forms completely. The documents required in the application form, the QMS documentation, and the technical documentation shall be submitted to MCA along with this form. The company declares that the information it has provided is correct and complete and agrees that any discrepancy may lead to variations in the terms and conditions of the agreement or termination of the agreement by signing the application form.

The application shall be made and the application forms shall be completed by an authorized person of the applicant company.

EU Authorised Representative of the company can make an application on behalf of the company.

**1.1.2.** MCA shall initiate the application review process upon receiving the application documents. It may require the company to provide additional documents other than those specified in the application form during this process. MCA may consult the Malta Medicines Authority, listed on the <https://medicinesauthority.gov.mt> website, based on their scope of coverage in Malta, or the competent authorities of other Member States during the process of application assessment. During the application, the company shall inform MCA of the missing parts of the technical documentation, together with a plan and declaration for completeness. MCA shall take into consideration this information. If the application review identifies missing parts for the technical documentation, the company shall submit these documents not later than the imposed deadline by MCA. If the required documentation is not received within maximum 15 days after the imposed date, MCA may cancel the application.

**1.1.3.** MCA may contact the previous Notified Body or Certification Body of the company or demand that the company provide the reports and documents issued by that Notified Body or Certification Body for transfer applications.

**1.1.4.** The application assessment may result positively or negatively. In case it is negative, the company shall be duly informed.

**1.1.5.** In case the application assessment results positively, an agreement shall be signed with the company.

**1.1.6.** Upon the signature of the agreement, the company shall perform the financial obligations provided in the agreement and submit all the documentation including specifically the technical documentation and Quality Management System Documentation, to MCA within maximum 15 days after the imposed date.

**1.1.7.** As for transfer applications, MCA may demand that the company and the previously Notified Body execute a transfer agreement with no financial value.

**1.1.8.** MCA may contact the previous Notified Body of the company for transfer applications and reject the application of the company according to the information given. If it is not possible to receive information from the previous Notified Body, MCA may evaluate the application as a new application or else reject it.

**1.1.9.** After the agreement is executed, the documentation submitted by the company shall be reviewed, and missing documents, if any, shall be determined and notified to the company. The company shall submit the missing documents within maximum 15 days after the imposed date. In the event that the documentation demanded is not provided by the company following the execution of the agreement, MCA may cancel the agreement.

**1.1.10.** In case of conflict during the applications, the company shall be required to provide additional information, and an application shall be lodged with the Competent Authority in which the company or its authorized representative is placed and request information regarding the resolution of the conflict. In cases where the company has no registered place of business in the European Union and has not yet designated an authorized representative, the matter shall be referred to the competent authority in which the person or organization to be appointed as the authorized representative has its registered place of business. The costs arising from the application shall be paid by the company.

**1.1.11.** For several devices, consultation with the authorities may be necessary. In this case, the related expenses shall be covered by the company. The company may not hold MCA for delays arising from the review conducted by the authorities.

**1.1.12.** Re-certification applications shall be lodged, agreements shall be signed, and the requirements of the agreements shall be fulfilled at least 12 months prior to the expiry date of the certificates. If the application is submitted less than 12 months before the expiry date, MCA may refuse the application following its evaluation. However, if such an application is accepted, the Company shall accept any deadline limitations for the correction of nonconformities identified during re-certification, as well as any potential waiting periods for authority consultations.

#### 1.2. Document Submission and Format of the Documents During Application

**1.2.1.** Supplementary documents to be provided during the applications and other technical documentation shall only be provided in digital form, and files shall only be sent to e-mail addresses using the maltaca.com domain. Only controlled copies of documents shall be shared with MCA. Hard copies of technical documentation shall not be accepted. All submitted technical documentation and any related correspondence for the application (including test results) shall be in the English language.

As a general principle, if any of the information requested in some part of technical documentation is not available in English, the manufacturer shall provide translations of documents (procedures, instructions, protocols, reports, etc.) in technical documentation.

**1.2.2.** Documents shall be provided as paginated, fully searchable, bookmarked PDF files. Other software formats may be acceptable, but it may result in a delay while files convert to a fully searchable bookmarked PDF format. PDF files and attachments shall not be file-protected or locked. For scanning directly from printed pages shall utilise Optical Character Recognition (OCR).

**1.2.3.** File names of technical documentation shall reflect the information covered within that part and the documents.

#### 1.3. Technical Documentation Completeness Check

At this stage, the submitted documentation is reviewed mainly for completeness in order to determine whether to proceed with the detailed technical documentation review. The findings/missing documentations that are reported in this stage shall be closed within the imposed deadline.

## **2. AUDITS**

**2.1.** Audits in the scope of the Regulation (EU) 2017/745 are one of the conformity assessment processes used for the assessment of conformity with Regulation (EU) 2017/745 by evaluating the quality management system. During the audits, the rules defined in Regulation (EU) 2017/745, EN ISO 13485 Annex-ZB, and EN ISO/IEC 17011 shall be taken into consideration.

**2.2.** Audits shall also cover the company's own rules for the applied scope.

**2.3.** Audits shall be performed according to MCA procedures. The sampling method shall be used for audits.

**2.4.** Any nonconformity revealed in the audits shall be recorded by means of a Finding Report. As part of the audits, the technical documentation prepared in line with the Regulation (EU) 2017/745 may be reviewed.

**2.5.** If any nonconformity revealed in audits requires a follow-up audit, this might be performed only if the corrective and preventive actions submitted by the company to MCA are found effective.

**2.6.** The audits may cover the critical sites and critical suppliers of the company. MCA shall determine which sites shall be audited.

**2.6.1.** Under normal conditions, the period granted for correcting nonconformities shall be maximum 4 month. If the company requests the relevant period to be extended for justifiable reasons, MCA may determine to extend the relevant period. It shall be noted that the maximum extension period to be granted might be for 1 more month. In order to be able to request extra time in case of a reported major non-conformity, the company shall have downgraded all major non-conformities to a minor level within 4 months.

**2.6.2.** Conformity assessment activities documentation shall be in the English Language. In case different languages are spoken, or some part of the QMS documentation is not available in English, in audits, the following actions shall be applied;

- An independent and impartial translator shall be assigned for the audits. In this situation, before assignment, the Confidentiality and Impartiality Commitment for Translators shall be signed by the translator and/or
- If the audit team includes a team member with the same native language as the company, that member can perform the audit without a translator.

### **2.7. Stage 1 Audits**

**2.7.1.** Stage 1 audits shall be performed during the initial assessment application. The purpose of those audits is to check whether or not the company is ready for the Regulation (EU) 2017/745 Stage 2 audit.

**2.7.2.** Stage 1 audits shall be performed off-site according to the rules defined in the procedures. Head of audit team may demand that the company ensure conference calls and provide video, images, etc., documents during the audits to be performed off-site.

**2.7.3.** If minor nonconformities are detected during Stage 1 audits, those nonconformities shall be checked during Stage 2 audits.

**2.7.4.** If major nonconformities are detected during Stage 1 audits, the company shall correct all nonconformities and provide the evidence documentation to MCA. If the detected nonconformities are corrected to a great extent and the remaining nonconformities do not obstruct the performance of Stage 2 audits, MCA shall inform the company of the remaining nonconformities, and they shall be checked during Stage 2 audits.

### **2.8. Stage 2 Audits**

**2.8.1.** These site audits shall be performed after stage 1 audits during the initial assessment applications. During the audits, a detailed assessment shall be performed to determine if the quality management system that is established and implemented, as well as the infrastructure conditions, comply with the requirements provided in the Regulation (EU) 2017/745.

**2.8.2.** The company shall submit to MCA the corrective and preventive actions for all nonconformities determined during Stage 2 audits.

### **2.9. Surveillance Audits**

**2.9.1.** The purpose of this audit is to perform a detailed review in order to determine whether the management systems and infrastructure conditions provided by the company for the product or service continue to conform to the requirements of Regulation (EU) 2017/745 as well as the effectiveness of post-market surveillance, clinical follow-up and vigilance systems created by the company for the continuation of the product and service safety and performance and availability of parallel implementations as declared by the company.

**2.9.2.** Some of the sections may be left outside the scope during surveillance audits, but MCA shall have assessed all the relevant points that are required to be assessed in a certification cycle, which is 5 years.

**2.9.3.** The first surveillance audit shall be performed in a maximum of 12 months after the certification date. Other routine surveillance audits shall be performed in a maximum of 12 months after the previous surveillance audit; however, MCA may choose to perform early surveillance audits.

**2.9.4.** Surveillance audits may cover testing where necessary. Samples may be taken from the company or market, and tests may be performed either by using the company's existing capabilities or by using 3rd party test laboratories.

### **2.10. Re-Certification Audits**

**2.10.1.** The purpose of this audit is to perform a detailed review in order to determine whether the management systems and infrastructure conditions provided by the company for the product or service continue to conform to the requirements of the Regulation (EU)2017/745 as well as the effectiveness of post-market surveillance, clinical follow-up and vigilance systems created by the company for the continuation of the product or service safety and performance and availability of parallel implementations as declared by the company.

**2.10.2.** All the necessary sections shall be audited under those audits.

**2.10.3.** If the last assessment task takes place less than 4 months before the expiration date of the certificates, the maximum time for closing non-conformities shall be limited to 15 working days before the expiration date of the certificates.

### **2.11. Transfer Audits**

**2.11.1.** The transfer audits are those performed due to transfer applications. If this audit is decided, the process shall be regarded as a new application. In this case, all sections shall be audited without excluding any of them.

**2.11.2.** The company shall provide to MCA the evidence of the corrective actions for all nonconformities independently of the nonconformity categories in transfer audits.

### **2.12. Scope Extension Audits**

**2.12.1.** When the company intends to extend the scope of the existing certificates, if MCA decides that the expansion requires an on-site audit, such audits shall be performed.

**2.12.2.** New agreements may be executed for scope extensions.

### **2.13. Change Audits**

**2.13.1.** These audits shall be performed to check if the changes made to the quality management system by the company are performed effectively and if the system that is changed continues to conform to the requirements of Regulation (EU) 2017/745. The company shall inform MCA of all changes that may affect the quality management system.

### **2.14. Unannounced Site Audits**

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**2.14.1.** The purpose of unannounced site audits is to evaluate the conditions related to product safety by means of a risk-based audit approach.

**2.14.2.** An unannounced site audit is only a part of Regulation (EU) 2017/745 Product Conformity Assessments.

**2.14.3.** The company shall not be informed of unannounced site audits.

**2.14.4.** The frequency of unannounced site audits shall be determined by MCA to be increased in case of necessity.

**2.14.5.** The critical sites and critical suppliers may also be audited under unannounced site audits. The company shall be responsible for receiving the necessary permit for audits to be conducted at critical suppliers. In that regard, the company shall execute agreements with critical suppliers about unannounced site audits.

**2.14.6.** Under unannounced site audits, samples may be taken from the company or market, and tests may be performed either by using the company's existing capabilities or by using 3<sup>rd</sup> party test laboratories.

**2.14.7.** The flow of unannounced site audits is different from that of the routine audits, and this flow shall be declared by MCA during the unannounced site audits. No audit plan shall be provided in advance.

**2.14.8.** The company shall inform MCA of annual shutdowns and non-manufacturing periods for all applicable sites, including those for critical suppliers. If the unannounced site audit team cannot reach the site during these periods, the unannounced site audit fee and audit team expenses shall still be invoiced to the company.

### 2.15. Critical Supplier Audits

**2.15.1.** The critical suppliers that may have an impact on product or service safety and performance of the company may be included in the scope of the audit as part of the routine audits.

**2.15.2.** Any nonconformity determined in relation to critical suppliers shall be reported to the company and not to the critical supplier.

**2.15.3.** The company shall be responsible for obtaining necessary permits for the audits to be conducted in critical suppliers and therefore, the company shall execute agreements about routine audits with the critical suppliers.

### 2.16. Follow-up Audits

**2.16.1.** Follow-up audits refer to the assessment of the correction of any nonconformity determined in an audit by means of the site audits. This audit is part of the audit in which the nonconformity has been determined.

**2.16.2.** The decision for a follow-up audit may be made for not only routine audits but also as certainly the correction of nonconformities determined as a result of the internal controls performed by MCA, checking the activities performed after suspension of the certificates, checking the nonconformities determined by the Competent Authorities, Authorities Responsible for Notified Bodies and EU Commission and checking vigilance system and post-market surveillance data.

**2.16.3.** Even if the audit team does not recommend any follow-up audit, the MCA certification committee may decide to perform a follow-up audit to check the nonconformity conditions.

**2.16.4.** The charges for the follow-up audit shall be calculated according to MCA pricing procedures and invoiced separately.

### 2.17. Hybrid Audits and Entirely Remote Audits

**2.17.1.** A hybrid audit is a method that includes both remote and on-site activities to assess compliance with MDR.

**2.17.2.** An entirely remote audit is an audit performed remotely using electronic means and no on-site activity plans with any auditor.

**2.17.3.** Entirely Remote Audits may also be used in exceptional or force majeure circumstances (e.g., war, natural disasters, pandemics) where on-site audits are not feasible, provided that an on-site audit shall be conducted within a reasonable timeframe. Following a remote audit, an on-site audit shall be performed within the timeframes defined in the procedures to support the entirely remote audit. If the on-site audit cannot be conducted, MCA may re-evaluate the validity status of the certificate.

**2.17.4.** All decisions on performing, stopping, canceling, invalidating, and repeating Hybrid Audits / Entirely Remote Audits shall be made solely by MCA.

**2.17.5.** All required IT, network, and software arrangements shall be initiated by the company prior to starting Hybrid Audit / Entirely Remote Audit, and the formal audit durations shall not be spent on these preparations and arrangements.

**2.17.6.** MCA may demand testing on IT, network, and software arrangements prior to the Hybrid Audit / Entirely Remote Audit.

**2.17.7.** Expenses due to stopping, cancelling, invalidating the Hybrid Audit shall be paid by the Company.

## 3. TECHNICAL DOCUMENTATION REVIEWS

**3.1.** One of the product conformity assessment processes under Regulation (EU) 2017/745 is the review of technical documentation.

**3.2.** Clinical assessment is included in the scope of technical documentation review activities.

**3.3.** Technical documentation activities may be part of the entire conformity assessment stages, and they may also be more than surveillance frequency, especially if the company has multiple technical documentation.

**3.4.** Technical documentation review activities shall be performed off-site.

**3.5.** Technical documentation review activities may be performed before or after the site audits. MCA may demand that the technical documentation review nonconformities to be united with the nonconformities determined at site audits, in case of necessity.

**3.6.** Nonconformities revealed in the technical documentation assessment shall be recorded by means of the Finding Report.

## 4. PROCESSES AFTER NONCONFORMITY REPORT

**4.1.** Nonconformities identified by MCA shall be documented in a Finding Report, which shall be subject to mutual approval. The Finding Report shall remain binding even if it is not approved by the company; however, the company may submit a written appeal regarding the identified nonconformities.

**4.2.** Based on the finding reports, the company shall fill in the Nonconformity Follow-up Report and submit it to MCA within a maximum 10 working days. The Company shall indicate the root cause of the nonconformities in addition to the corrections and the plan for corrective actions in this form. While making the planning, it is necessary to take into account the duration, nature, and emergency of nonconformity, and conformity to MCA procedures.

**4.3.** Nonconformity Follow-up Report provided by the company shall be assessed by the assessment team, as a result of which either it shall be approved, or corrections shall be demanded. The time spent on submitting, evaluating, and approving the Nonconformity Follow-up Report shall be included in the maximum available timeframe allowed for effectively closing the non-conformities.

**4.4.** The company shall perform the corrective actions and corrections with due regard for the activities and durations available in the duly approved Nonconformity Follow-up Report.

**4.5.** In case the closing of corrective actions is required to be approved by MCA, the company shall submit the evidence of corrective actions to MCA within a defined deadline. The corrective actions shall be

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assessed by MCA, and as a result of this assessment, they shall be either approved or rejected.

### 5. CERTIFICATION COMMITTEE

**5.1.** The certification committee established by MCA shall make a decision on product conformity assessment activities.

**5.2.** The certification committee shall be authorized to make such decisions as issuing, suspending, withdrawing, releasing suspension of certificates as a result of audits conducted in a normal manner.

**5.3.** The certification committee may make decisions for suspending, reinstating, and withdrawing certificates in case of critical nonconformities requiring technical assessment and following the control of the nonconformities.

**5.4.** The certification committee may decrease the validity period of certificates based on technical concerns.

**5.5.** Committee members decide within the framework of the matters stated below;

- based on the assessment documentation and additional information available, whether the requirements of Regulation (EU) 2017/745 are fulfilled,
- based on the results of its assessment of the clinical evaluation and risk management, whether the post-market surveillance plan, including the PMCF plan, is adequate,
- decide on specific milestones for further review by MCA of the up-to-date clinical evaluation,
- decide whether specific conditions or provisions need to be defined for the certification,
- decide, based on the novelty, risk classification, clinical evaluation, and conclusions from the risk analysis of the device, on a period of certification not exceeding five years.
- decide the acceptability of reports based on the majority of details of the level of justifications provided by the assessment team.
- whether special procedures of Regulation (EU) 2017/745, such as consultation procedures, are performed correctly,

### 6. ISSUING CERTIFICATES

**6.1.** After the assessment activities result positively, MCA shall issue an EU Certificate according to the application in the name of the company.

**6.2.** MCA shall decide how many certificates to issue. MCA issues a certificate or certificates in accordance with the minimum requirements laid down in Annex XII Regulation (EU) 2017/745 for a period of validity not exceeding five years and shall indicate whether there are specific conditions or limitations associated with the certification. Specific conditions or limitations shall be issued on certificates.

MCA shall issue the certificate(s) only for one company and shall not issue certificate(s) covering multiple entities. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system (EUDAMED) referred to in Article 30 of Regulation (EU) 2017/745.

**6.3.** The issued certificates and information about their validity shall be published on [www.maltaca.com](http://www.maltaca.com).

**6.4.** All the details about the Regulation (EU) 2017/745 certificates shall be disclosed to the Competent Authority. Certificates shall be entered into the electronic system referred to in Article 57 of Regulation (EU) 2017/745. Whenever the status of the certificate (withdrawn, suspension, restriction, etc.) and any information of the certificate are changed, the update shall be reflected in the EUDAMED.

**6.5.** MCA reserves the right to change the terms and the validity period of the certificates in case of a revision of a regulation, directive, standard, or legislation.

**6.6.** Certificates shall be drawn up in English. MCA shall issue the validity of certificates for 5 years.

**6.7.** Each certificate shall refer to only one conformity assessment route.

**6.8.** The scope of the certificates shall unambiguously identify the device or devices covered:

- a. EU technical documentation assessment certificates shall include a clear identification, including the name, model and type, of the device or devices, the intended purpose, as included by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment route, risk classification and the Basic UDI-DI as referred to in Article 27(6) 30 of Regulation (EU) 2017/745.
- b. EU quality management system certificates and EU quality assurance certificates shall include the identification of the devices or groups of devices, the risk classification, and the intended purpose for class IIb devices.

**6.9.** MCA shall be able to demonstrate on request which (individual) devices are covered by the certificate. MCA shall have a system that enables the determination of the devices, including their classification, covered by the certificate, with the app software system.

**6.10.** Certificates shall contain, if applicable, a note that, for the placing on the market of the device or devices it covers, another certificate issued in accordance with this Regulation is required.

**6.11.** EU quality management system certificates and EU quality assurance certificates for class I devices for which the involvement of the Notified Body is required pursuant to Article 52(7) shall include a statement that the evaluation by the MCA of the quality management system was limited to the aspects required under that paragraph. For sterile systems and procedure packs, the certificates shall contain a statement that the evaluation is restricted to aspects of the sterilization procedure for ensuring sterility until the sterile package is opened or damaged.

**6.12.** Where a certificate is supplemented, modified, or reissued, the new certificate shall contain a reference to the preceding certificate and its date of issue, with identification of the changes.

### 7. SUSPENSION AND WITHDRAWAL OF CERTIFICATES

The certificates shall be suspended or withdrawn in the event that the company fails to perform the conditions specified in the agreement, Medical Devices General Terms, and MCA procedures, undertake the actions determined by MCA, notify any substantial change, and any nonconformity determined in relation to the products and under similar conditions. The detailed conditions for suspension and withdrawal are defined below but MCA is entitled to withdraw the certificates for each condition that creates a basis for suspension according to project risks.

#### 7.1. Suspension of Certificates

**7.1.1.** MCA may suspend the issued certificates when the following conditions are applicable:

- Failure to submit an action plan for the nonconformities determined as a result of the audits and technical documentation reviews, failure to correct the nonconformities in a timely manner, inadequacy of activities with respect to correction of nonconformities,
- Determination of serious nonconformities that would cast suspicion on the functionality of the quality management system,
- Failure of the company to make adequate cooperation for planning and performance of audits,
- Determination of the fact that the company has not fulfilled the legal requirements completely,
- Voluntary request of the company for suspension of certificates,
- Misuse of CE marking, Notified Body number, MCA brands and logos,
- Conditions that may discredit product safety, product safety issues or lack of insufficient clinical evidence and pose potential threat on human health and safety,
- Failure of the customer to perform its financial obligations completely,
- Failure to inform MCA of substantial changes,
- Failure of the company to inform MCA of the vigilance system records, recall decisions, warning cases, findings of competent authorities, critical post-market surveillance findings,

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- The vigilance system records, recall decisions, warning cases, critical findings, and notifications of Malta Medicines Authority (MMA) and other competent authorities related to products, critical post-market surveillance findings related to products,
- Discrepancy between the information declared in the technical documentation and practice,
- Failure of the company to authorize MCA personnel to visit all the sites in all audits including unannounced site audits in addition to restricting access to documentation, preventing the personnel from conducting detailed queries, abandoning the personnel, failing to take sufficient safety measures for the personnel, keeping the personnel waiting for a long time, applying pressure on the personnel, threatening the personnel,
- Determination of the fact that the company has marketed the products having the reference number of another notified body after MCA has issued a certificate with the same scope, without receiving consent from MCA.

**7.1.2.** The certificates may not be used as of the date of suspension. New manufacture may not be realized, and all references to the MCA brand and services shall be suspended as long as the certificates are suspended. Otherwise, MCA may initiate legal action.

**7.1.3.** The company shall be informed of the suspension of certificates in writing, which shall include information as to how long the certificates may remain suspended and when they shall be withdrawn unless necessary actions are taken.

**7.1.4.** Suspension of Regulation (EU) 2017/745 certificates shall be notified to the competent authorities through EUDAMED or through other applicable ways until EUDAMED is fully functional.

**7.1.5.** Decisions for suspension and removal of suspension shall be made by the MCA Certification Committee with respect to matters requiring technical assessment.

### **7.2. Withdrawing or Restricting the Scope of Certificates**

**7.2.1.** The scope of the certificates may be restricted if the company fails to perform the requirements specified in Regulation (EU) 2017/745 and MCA documentation with respect to matters related to only a specific part of the certified scope.

**7.2.2.** MCA may withdraw the certificates if the company fail to perform sufficient and effective correction for the suspended certificates during the period of suspension.

**7.2.3.** MCA may directly withdraw without a suspension period the certificates when the following conditions are applicable:

- Failure of the company to perform its financial obligations,
- Repeating failures to the contractual obligations
- Direct (intentional) violation of the contract terms.
- Determination of the fact that the company repeatedly commits mistakes leading to suspension,
- Repeating the same major non-conformities that require suspension
- If the company declares that it shall not fulfill any requirement,
- If the company demands withdrawal of the certificate of its own will.
- If the company gives incorrect, falsified, and misleading information,
- Use of CE marking in products not certified by MCA.
- The vigilance system records, recall decisions, warning cases, critical findings, and notifications of Malta Medicines Authority (MMA) and other competent authorities related to public health and safety, critical post-market surveillance findings related to products.
- Declaring or performing acts that disallow MCA from executing conformity assessment tasks.
- Obvious intentional acts that may decrease the reputation of MCA.

**7.2.4.** Whenever the certificates are withdrawn and restricted in terms of scope, the company shall be informed of this fact in writing. Withdrawal of Regulation (EU) 2017/745 certificates shall be notified to the competent authorities through EUDAMED or through other applicable ways until EUDAMED is fully functional.

**7.2.5.** If the company persists in using the certificates, CE marking, MCA brand, and logos after withdrawal, MCA may take legal action.

## **8. RIGHTS AND OBLIGATIONS OF MCA**

**8.1** MCA and all the employees shall keep confidential all kinds of information given by the companies and related parties concerning conformity assessment activities, and they shall not disclose the relevant information to third parties under any circumstances. Nevertheless, the information may be disclosed to the Competent Authority, Authorities Responsible for notified bodies, the European Commission, or courts upon demand. If MCA becomes obliged to give information to third parties due to legal reasons, it shall inform the relevant company unless it is legally impermissible.

**8.2** MCA shall perform all of the activities without racial, language, and religious segregation.

**8.3** As part of its duties, MCA has signed a Confidentiality and Impartiality Commitment with its employees.

**8.4** MCA shall be obliged to inform the certified companies of material changes in the conformity assessment system (standard procedures or rules) as soon as possible in order to enable them to make the necessary arrangements within the transition period. Web page, e-mail, etc., may be used for that purpose.

**8.5** MCA shall be entitled to make changes in conformity assessment and pricing procedures. It may make changes in the duration of the audit based on the approval of the head of audit team and the relevant department supervisor, according to the conditions that may arise during the audit.

**8.6** MCA shall be responsible for announcing the companies receiving certificates and becoming subject to suspension and withdrawal of certificates on its web page.

**8.7** If MCA, in its own discretion, waives from acting as a notified body or its activities are suspended by the relevant Authorities Responsible for notified bodies, the documentation of the company shall be submitted to a notified body to be determined by the company. In that case, the conditions of the new notified body shall be valid for certification, and MCA shall not have any right of disposition on those conditions.

**8.8** MCA undertakes to comply with the documentation of the Competent Authority, Authorities Responsible for notified bodies, European Commission concerning notified bodies and certification bodies, in addition to the above-mentioned requirements.

**8.9** MCA may amend the terms of the agreement or cancel the agreement according to the outcome of the application assessment process.

**8.10** MCA may cancel the agreement in case the company fails to fulfill any contractual obligation.

**8.11** MCA may amend the terms of the agreement or cancel the agreement if it is ascertained that there is any change in the information given in the application process during the technical documentation review.

**8.12** If, during the audits, any information regarding the number of company employees, product range, site scope, critical supplier scope, etc., is found to be different from the one indicated in the application form, MCA may alter the audit period and charges according to its procedures and issue invoices to the company for the difference.

**8.13** MCA may subcontract the product conformity assessment processes partially in case of necessity. The details of the activities to be subcontracted and the subcontractor shall be shared with the company, and unless any appeal is made within 5 business days, the subcontractor shall be considered to have been accepted by the company. Even in the case of subcontracted activities, MCA shall remain responsible for the certification decision as well as all the relevant activities.

**8.14** MCA may make variations in the pricing of surveillance audit or other charges after the agreement is signed. In such cases, it shall duly inform the company of the change. If the company does not give consent to the change of prices, MCA may cancel the agreement

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unilaterally. MCA will publish the current available fees on [www.maltaca.com](http://www.maltaca.com)

**8.15** If the company wishes to cancel the agreement during the performance of any service, including off-site reviews, it shall be possible to issue an invoice to the company for the value of the activities performed for the service during the period until the cancellation date, even if the relevant service has not been completed.

**8.16** If the company make a request to transfer valid certificates issued by MCA to another Notified Body, the certificates are withdrawn by the Certification Committee, and the contract is terminated on the transfer date or the expiry date of the validity period of certificates, whichever is earlier. MCA shall submit all relevant documentation to the Incoming Notified Body. In this situation, it shall be possible to issue an invoice to the company as mentioned above.

**8.17** It may demand that the company recall products in case of any effect on human health and product safety.

**8.18** It may conduct an extra off-site review, follow-up audit, or unannounced site audit according to the findings determined through the internal audits of MCA, as well as the audits performed by the European Commission, Competent Authority, and Authorities Responsible for notified bodies.

**8.19** It may cancel the agreement unless the company provides the necessary documentation within 15 days from the signature of the agreement.

**8.20** MCA may demand an interpreter or all kinds of document translation in case the assessment team, including the committee members, does not know the local language of the company.

**8.21** MCA shall keep all documentation that needs to be uploaded to EUDAMED, according to the Quality Records Procedure, until EUDAMED is fully functional. When EUDAMED becomes functional, all necessary documentation shall be uploaded to the EUDAMED database by the Committee and Competent Authority Communication Coordinator according to the Procedure for Legal Notification Consultation Coordination and Communication for Regulation (EU) 2017/745. If Malta Medicines Authority (MMA) or other authorities have any notifications related to documents that shall be uploaded to EUDAMED, MCA shall apply its notifications in its Quality Management System until EUDAMED is functional.

**8.22 Surveillance activities and post-certification monitoring**  
MCA in question shall, upon receipt of information about vigilance cases from a manufacturer or competent authorities, decide which of the following options to apply:

- not to take action on the basis that the vigilance case is clearly not related to the certification granted,
- observe the manufacturer's and competent authority's activities and the results of the manufacturer's investigation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken,
- perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced site audits, and product testing, where it is likely that the certification granted is at risk,
- increase the frequency of surveillance audits,
- review specific products or processes on the occasion of the next audit of the manufacturer, or
- take any other relevant measures related to situations
- where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw.

**8.23** If MCA decides to cease its conformity assessment activities, it shall inform the Malta Medicines Authority (MMA) and the certified manufacturers as soon as possible and, in the case of a planned cessation, not later than one year before ceasing its activities. MCA shall first communicate with Malta Medicines Authority (MMA) for the period for which the certificates will remain valid after ceasing the activities. Once the roadmap is finalized, MCA shall inform its manufacturers. The certificates may remain valid for a temporary period of 9 months after cessation of MCA's activities on condition that another Notified Body has confirmed in writing that it will assume responsibilities for the devices covered by those certificates

**8.24** Where MCA's designation has been suspended, restricted, or fully or partially withdrawn, it shall inform the manufacturers concerned at the latest within 10 days.

**8.25** If MCA decides to take over the certificates of a Notified Body that ceases its activities, it shall confirm in writing to the relevant competent authorities that it will assume responsibilities for the devices covered by those certificates.

**8.26** If MCA decides to take over the certificates of a withdrawn Notified Body, Malta Medicines Authority (MMA) or MCA shall immediately inform the Commission, the other Member States, and the other notified bodies thereof. MCA shall confirm in writing to the relevant competent authorities that it will assume immediate responsibilities for the devices and will have completed an assessment of them within 12 months of the withdrawal of the designation.

## 9. RIGHTS AND OBLIGATIONS OF THE COMPANY

**9.1.** The company shall provide correct information during the entire assessment process, including the application, and accept all the sanctions that shall arise from failure to fulfill this obligation.

**9.2.** The company shall be obliged to comply with all kinds of written information and instructions received from MCA concerning the operation of the management system and product conformity assessment under the relevant Standard and Regulation.

**9.3.** Following the certification of its management system or product under the management system, shall be obliged to assign an executive to be responsible for ensuring the implementation and continuation of the established system, making it possible for the audit team to have access to all the necessary sites during office hours, guarantee that the requirements of the directive, standards related to the product, if any, or the domestic and international documentation binding on the manufacturer are satisfied with respect to the certified product.

**9.4.** Observers, guides, and candidate auditors/experts may accompany MCA in the audits or unannounced site audits that it shall perform on the site or office of the company. An observer may be any person who observes a member of the audit team or else a representative of the customer or the Authorities Responsible for notified bodies, the EU Commission, or Competent Authorities. A guide, on the other hand, is the person accompanying the audit team for assistance. A guide may be assigned for each member of the audit team. The guide shall be responsible for ensuring communication, arranging contacts, organizing site visits, ensuring implementation of safety rules on site, witnessing the audit in the name of the customer, or providing the information demanded by the auditor. Information shall be given to the customer and members of the audit team, and approval shall be received from the company regarding the participation of guides and observers in the audit, excluding unannounced site audits.

**9.5.** The company shall be obliged to provide all kinds of written and verbal information required for the audit to the relevant people, including MCA personnel and to the representatives of Authorities Responsible for notified bodies, the EU Commission, or Competent Authorities.

**9.6.** The company shall submit plans for changes that can affect MCA's audit and technical documentation review tasks, data presented on the certificates and agreements, data used for MCA's planning activities, legal changes, critical personnel changes and substantial changes in the approved quality management system or systems or to the product-range covered, the approved design of a device, the intended use of or claims made for the device and any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with Section 4.5.6 of Annex VII of MDR in 5 business days. The submission shall include a plan for changes. The changes shall not be implemented prior to the review of MCA. For reporting substantial changes, the company shall use the Change Notification Form available at [www.maltaca.com](http://www.maltaca.com). This form may include some examples for changes to be reported, but it should be noted that the items listed in the Change Notification Form is not exhaustive, and changes that may not fall in the defined types shall be reported by selecting "other" in this form. If the company is not sure whether a change needs to be reported to MCA or not, it shall report anyway.

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Examples of main change topics to be reported (not exhaustive)

- Change of the legal and commercial standing of the entity,
- Change of company partnership structure,
- Changes in key personnel of the enterprise,
- Changes in notification address and operating areas, relocation, new locations,
- Changes in critical suppliers and subcontractors,
- Changes in critical personnel,
- Change of the scope of the approved quality management system or systems or to the product-range covered,
- Changes in the QMS structure and procedures for MDR compliance,
- Changes in the validated processes,
- Changes in the controlled environments,
- Changes in EU Authorized Representative,
- Changes to the EU-type examination test and certificates,
- Change of the intended use of or claims made for the device,
- Change of the approved performance of the device,
- Change in the critical components
- Change in the variants
- Change of any substance incorporated in or utilised for the manufacturing of a device and being subject to the specific procedures in accordance with the specific procedures of the Regulation (EU) 2017/745.

The company shall immediately inform MCA of any change that may occur in technical documentation after certification, and the product shall not be marketed without receiving consent from MCA.

**9.7.** The company shall be obliged to inform MCA of vigilance system records, incidents, recall decisions, warning cases, findings of competent authorities, and critical post-market surveillance findings immediately and not later than 5 business days. The timescale for incident reporting shall be applied regarding the requirements of Regulation (EU) 2017/745 by the company. MCA shall evaluate the company about vigilance situations and decide which of the following options to apply; not to take action on the basis that the vigilance case is clearly not related to the certification granted, observe the company's and competent authority's activities and the results of the company's evaluation so as to determine whether the certification granted is at risk or whether adequate corrective action has been taken, perform extraordinary surveillance measures, such as document reviews, short-notice or unannounced site audits and product testing, where it is likely that the certification granted is at risk, increase the frequency of surveillance audits, review specific products or processes on the occasion of the next audit of the company or take any other relevant measure related situations.

**9.8.** The company shall be obliged to record the appeals or complaints posed by the customer or third parties under the certificate and communicate them to MCA.

**9.9.** The company shall be obliged to inform MCA and competent authorities for vigilance cases of the products certified by MCA according to the Regulation (EU) 2017/745 after these devices enter the market.

The company shall fulfill the requirements of Regulation (EU)2017/745 Articles 87, 88, and 89 for Vigilance.

The company shall be responsible for notifying MCA and the relevant Competent Authorities for any Serious Incident, Field Safety Corrective Action, Field Safety Notice, Periodic Summary Reports, Trend Reports, Recalls, and other competent authority requests within the defined periods in (EU)2017/745 Articles 87, 88, and 89.

If, after becoming aware of a potentially reportable incident, the company is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the required timeframe. This includes cases where the company does not retrieve objective evidence or information about the non-existence of a causal relationship between the incident and the device.

To ensure timely reporting, the manufacturer may provide an initial report before a full report when necessary.

The company shall report its field safety corrective action without delay before executing the action, except for emergencies that require immediate field safety corrective action.

If the company considers that the incident is not a serious incident or is an "expected undesirable side effect" that will be covered by trend reporting in accordance with Regulation (EU)2017/745 Article 88, it shall submit an explanatory statement to MCA and the relevant Competent Authorities.

**9.10.** The company shall be obliged to submit the technical documentation in executed, approved, and controlled copies to MCA. This rule shall apply to the documentation to be submitted in digital media. All of the documentation to be submitted shall be in English.

**9.11.** The company shall be obliged to preserve all the records related to the activities performed by MCA (agreement, report, CAPA records, etc.) during the validity period of the certificate unless otherwise specified in the relevant directive or legal regulation.

**9.12.** The company shall be obliged to submit all the papers and documents required for the application to the MCA in a timely manner.

**9.13.** MCA may conduct additional audits for a certain charge when required to evaluate the impact of the changes on the system or product.

**9.14.** The company shall perform the requirements of important changes that may occur in the assessment system of MCA (concerning standard procedures or rules) within the transition period that is notified to it.

**9.15.** The company shall be obliged to comply with the Certificate and CE Mark Usage Procedure, this text (Medical Devices General Terms), and similar MCA procedures of which updated versions are available at [www.maltaca.com](http://www.maltaca.com), and keep up with their updated versions.

**9.16.** The company shall be obliged to pay the fees indicated in the pricing instruction and service agreement, and the fees for special or follow-up audits provided in the relevant standard or regulation.

**9.17.** The company shall be obliged to discontinue using the MCA brand and notify the body identification number and certificate after the certificate is suspended or withdrawn. It shall be obliged to discontinue using all kinds of documents and promotion materials making reference to the certificate, brand, or notified body identification number, and return the certificate to MCA when necessary.

**9.18.** The company shall be obliged to comply with the local/international legal regulations and laws, directives, and standards related to its activities.

**9.19.** The company may submit its complaints regarding MCA conformity assessment activities and appeals to its decisions as mentioned in the Complaints and Appeals Assessment Procedure. MCA makes the necessary assessment within the scope of the Complaints and Appeals Assessment Procedure and informs the company. The company has the right to appeal to MCA for the second time regarding the decision taken by the appeal committee and the activity carried out. If the company does not accept the decision of the appeal committee for the second time, the firm may apply to the relevant legal authority. If MCA is in excess of the period granted for resolving the appeal as indicated in the Complaints and Appeals Assessment Procedure, the company may file an application to the relevant legal authority in the same manner. The company may appeal to a decision taken by MCA regarding itself within 10 business days by providing justifications for the appeal. The company shall assume the expenses incurred for the experts, the committee to be established for complaints and objections, and similar costs.

**9.20.** The company shall be obliged to inform the name of the notified body and justifications for withdrawal if any agreement has been signed with another Notified Body about the products subject to the application under Regulation (EU) 2017/745.

**9.21.** The company shall be obliged to indicate the name of the notified body and document type if there is/are any valid/invalid certificate/certificates issued by another Notified Body for the products subject to the application. If the certificates are invalid, they shall indicate the justifications for the invalidity.

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**9.22.** The company shall be obliged to inform MCA of the reason for rejection if any of its applications have been rejected by another Notified Body for the products subject to the application (along with the name of the notified body, its decision, and justifications).

**9.23.** The company shall be responsible for designing and manufacturing the product/products in line with the essential or other legal requirements specified in the relevant European harmonized standards, Common Specifications, and national regulations and keeping up with the updated version of this regulation and implementing the changes. The company may develop alternative methods instead of fully complying with any harmonized standard, in which case it shall be responsible for proving and explaining in detail that the methods meet the essential requirement of the Regulation (EU) 2017/745.

**9.24.** The company shall be obliged to accept and make payment for the invoices issued by MCA prior to the implementation of activities subject to the conformity assessment process.

**9.25.** The company shall agree that the agreement, which is duly signed, shall not be construed as an entitlement to the certificate.

**9.26.** The company accepts and makes payment for the invoices issued by MCA for the duly completed services, even if the result is negative.

**9.27.** Once the agreement is signed, MCA allocates resources to handle the project from start to end. Therefore, the cancellation of the agreement shall not eliminate the obligation of the company to pay for the services. If the agreement is cancelled by the company, the amount paid up to the termination date shall be a non-refundable fee and shall be considered as a termination fee. Similarly, if the company decides to narrow the scope of the agreement by withdrawing certain scopes/products, only 15% of the fee calculated specifically for the withdrawn scopes/products shall be refunded.

**9.28.** The company shall serve a written notice if it intends to terminate the agreement.

**9.29.** The company shall make timely payments.

**9.30.** The company shall accept and make payment for the invoice issued for the activities performed for a service, even if that service has not been completed in the event that the agreement is terminated during the period MCA performs any service.

**9.31.** The company shall submit all the declarations and documents required by MCA within a maximum of 15 days if the company intends to transfer any certificate issued by MCA to another notified body.

**9.32.** If the company intends to transfer any certificate issued by another notified body to MCA, it shall submit the documents required by MCA within a maximum of 15 days. In case of any such certificate transfer demand, it shall accept that MCA may contact the existing notified body. It shall also agree that MCA may cancel the agreement during the application assessment stage according to the information given by the notified body. If the notified body does not give any response within a maximum of 15 days, MCA may suspend the certificate transfer process.

**9.33.** If the company intends to transfer any certificate issued by MCA to another notified body, the company shall inform MCA at least 2 months before. The company shall submit all necessary information and documentation for the transfer assessment. The company shall cover the cost of the relevant committee, experts, and similar other costs to be incurred in relation to the transfer assessment.

**9.34.** In case of any such certificate transfer demand, it shall accept that MCA may contact the existing notified body. It shall also agree that MCA may cancel the agreement during the application assessment stage according to the information given by the notified body. If the notified body does not give any response within a maximum of 15 days, MCA may suspend the certificate transfer process.

**9.35.** The company shall not implement any substantial changes without receiving consent from MCA.

**9.36.** The company shall complete the visa invitation form to be provided in the attachment to the agreement to give permission for

unannounced site audits in advance, and also provide a visa invitation letter to MCA, additionally, in case of such demand.

**9.37.** The company shall authorize MCA personnel to visit all of the sites, including design, manufacture, warehouse, test, and examination sites, to ask questions to employees assigned to those sites, and examine the products and documents in all of the sites.

**9.38.** The company shall allow MCA personnel to make intensive and detailed questioning in case of necessity.

**9.39.** The company shall agree to and allow all the audits to be conducted by MCA at the site of the company, including unannounced site audits.

**9.40.** The company shall give consent to all the audits, including unannounced site audits and witness audits, to be conducted by Authorities Responsible for notified bodies, European Commission, and other relevant authorities at the site of the company and entitle the representatives of those authorities to make audits on its site along with MCA.

**9.41.** The company shall make agreements with suppliers and subcontractors in order to ensure that all kinds of audits, including unannounced site audits and witness audits, may be performed by MCA and witnessed by the representatives of Authorities Responsible for Notified Bodies, European Commission, and other Competent Authorities concerning the critical suppliers and subcontractors. The company shall accept the sanctions to be applicable in case critical suppliers and subcontractors do not give consent to such audits.

**9.42.** The company shall allow MCA to choose products from its warehouse for examination purposes and conduct quality assurance tests on them during routine audits.

**9.43.** The company shall agree that MCA shall not offer any consultancy services to the company in relation to the services provided above and shall not make any such demand.

**9.44.** The company shall ensure that the necessary information is given and the necessary measures are taken for protecting the safety and health of the personnel assigned by MCA, as well as the accompanying employees. The necessary equipment shall be provided by the company.

**9.45.** The company shall agree that MCA shall not be responsible for any loss incurred as a result of the termination of Accreditation or Notification of MCA and shall not make any demands for those reasons.

**9.46.** The company shall not file an application to more than one Notified Body for the same products simultaneously.

**9.47.** The company shall use the brand, logo and CE marking of MCA with due regard for the rules determined by MCA. It shall not use the brand, logo, and CE marking in case of suspension or withdrawal of certificates.

**9.48.** The company shall accept all the responsibilities that shall arise from suspension or withdrawal of certificates, including those to the customers, and shall not hold MCA responsible for that.

**9.49.** The company shall fully comply with the nonconformity closure dates declared after the assessments, follow up on those dates, and shall not hold MCA responsible in case of failure in due observance of those dates. It shall be accepted that the certificate may be suspended if the nonconformities cannot be closed within those dates.

**9.50.** The company shall agree that MCA shall not be responsible for reminding the expiration of nonconformity closure dates or any other date specified for any pending response.

**9.51.** The company shall not market any products with the identification number of another notified body without receiving consent from MCA after MCA issues a certificate with the same scope.

**9.52.** The company shall not undertake the manufacture and sale of products with CE marking when the certificate is subject to suspension and withdrawal or its validity period has expired.

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**9.53.** The company shall not use CE marking for products not certified by MCA.

**9.54.** The company shall accept the findings of the extra off-site review, committee review, follow-up audit, or unannounced site audit according to the findings determined through the MCA internal audits and audits conducted by the European Commission and Competent Authorities and Authorities Responsible for Notified Bodies, and make corrections within a defined due time.

**9.55.** The company shall cover the cost of the relevant committee, experts, and similar other costs to be incurred in relation to the appeals.

**9.56.** Companies shall inform MCA about all the substantial changes related to their critical suppliers, including the changes in the critical supplier's certificates in maximum of 5 business days.

**9.57.** MCA shall not make any refund in case of delay of a responsibility of the company, such as technical documentation sending, nonconformity closure, etc., and having caused a delay in any responsibility while carrying out the projects, which may cause MCA not to be able to allocate efficient resource planning and effective assessment.

**9.58.** The company shall create all applicable documents according to Regulation (EU) 2017/745, regardless of whether EUDAMED is functional in whole or in part, and submit them to MCA. Once EUDAMED is actively working, all necessary documents shall be uploaded to EUDAMED.

**9.59.** When complying with imposed deadlines, the company shall consider the availability of MCA resources and the time needed for planning. The company shall not make MCA responsible for the inability to allocate necessary resources when the response is provided closer to the end deadlines, which may affect the validity of the certificates. The company shall be responsible for communicating and confirming with MCA to check the time needed for resource allocation and planning when considering the response time.

**9.60.** Where a company certified by an MDD Notified Body wants to transfer the surveillance requirements of its certified products to MCA, applications for surveillance assessment transfer shall be received only if the following issues are fulfilled.

In accordance with Article 120 (3c) Regulation (EU) 2017/745, in cases within this scope;

- (a) Those devices continue to comply with Directive 93/42/EEC as applicable.
- (b) There are no significant changes in the design and the intended purpose.
- (c) The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health.
- (d) No later than 26 May 2024, the company has put in place a quality management system in accordance with Article 10(9);
- (e) No later than 26 May 2024, the company or the authorized representative has lodged a formal application with MCA for conformity assessment of the certified device or a device intended to replace this device, and no later than 26 September 2024, MCA and the manufacturer shall sign a written agreement under the second subparagraph of Section 4.3 of MDR Annex VII.

**9.61.** MCA shall apply the requirements of the MDR on post-market surveillance, market surveillance, and audit, vigilance, registration of economic operators and devices in place of the requirements corresponding to the Medical Device Directive 93/42/EEC for devices referred to in Article 10.64.

**9.62.** The surveillance assessment transfer application of the manufacturer shall be received by the Sales Unit with the Application Form Related to Transfer of Surveillance Assessments Form and approved proof documents requested in this annex until 26 May 2024, and MCA and the manufacturer shall sign a written agreement specified in Article 10.59 (e), no later than 26 September 2024. At the same time, the Confirmation Letter shall be published by MCA, and a "Manufacturer Declaration" shall be requested from the manufacturer.

**9.63.** After the necessary documents are completed, planning is made according to the Medical Devices Audit and technical documentation Review Planning Procedure, and the final decision on the appropriateness of the transfer shall be made according to the

Medical Devices Product Conformity Assessment Procedure.

**9.64.** When necessary, approvals are obtained, Sales Unit shall document (EU) 2017/745 Regulation Product Conformity Assessment Agreement, Medical Devices General Terms, Transfer Agreement for Surveillance of Legacy Devices, and Duration and Fee Calculation Form.

**9.65.** In accordance with Article 120 (3a) (EU) 2017/745 Regulation, certificates issued under Directive 93/42/EEC as of 25 May 2017 and still valid on 26 May 2021 shall remain valid until the following dates for the relevant risk class of the devices after the expiry of the period specified in the certificate:

- a) 31 December 2027, for all class III devices, and for class IIb implantable devices except WET devices (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors);
- b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

**9.66.** In surveillance assessments for devices referred to in paragraphs 10.59(a) and (b), the requirements of the MDR on post-market surveillance, market surveillance, and surveillance, vigilance, registration of economic operators and devices apply instead of the corresponding requirements in Directive 93/42/EC.

**9.67.** Until 26 September 2024, unless the company agrees with MCA that it will carry out the surveillance specified in Article 10.60, MDD Notified Body shall continue to be responsible for the necessary surveillance audit for all applicable requirements of 93/42/EEC, provided that there is no significant change in the design and the intended use of the devices it has certified.

**9.68.** No later than 26 September 2024, MCA, which has signed the (EU) 2017/745 Regulation Product Conformity Assessment Agreement, shall be responsible for the surveillance in respect of the devices covered by the written agreement. In cases where the written agreement covers a device intended to replace a device with a certificate issued under Directive 93/42/EEC, the surveillance shall be carried out according to the device (within the scope of the current certificate) to be replaced.

**9.69.** Arrangements for the transfer of surveillance from MDD Notified Body to the MCA shall be clearly defined in an agreement between the COMPANY, MDD Notified Body, and MCA, where applicable. MCA shall not be responsible for the conformity assessment activities carried out by the MDD Notified Body.

**9.70.** Regulation (EU) 2017/745 and amendments of the Regulation (EU) 2023/607, the man/day fee is determined according to the resources to be spent on surveillance transfers.

**9.71.** MCA may use its own software ecosystem for interaction during the conformity assessment process. In such cases, the Company shall accept that any item assigned to it through this software shall be deemed legally binding and shall ensure a timely response and data entry within the relevant software system.

### **9.72. Audits to be Carried Out in Coordination with MCA Subcontractor SZUTEST Uygunluk Değerlendirme A.Ş.**

In cases where a company has submitted an (EU) 2017/745 conformity assessment application together with a request for ISO 13485 QMS certification to SZUTEST Uygunluk Değerlendirme A.Ş., the audits may be conducted in coordination with each other under a scope equivalent to the requirements of (EU) 2017/745.

All decisions regarding the coordination of these audits, including whether they will be carried out consecutively or independently, shall be entirely at the discretion of MCA.

The company shall acknowledge that all information and objective evidence obtained during audits conducted under a scope equivalent to the requirements of the Regulation (EU) 2017/745 may also be used within the scope of ISO 13485 QMS certification.

Furthermore, the company shall accept that MCA may contact SZUTEST Uygunluk Değerlendirme A.Ş. for the purpose of audit

planning and information exchange within the framework of this coordination.

## 10. TRANSITIONAL PROVISIONS FOR CERTAIN PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE LISTED IN ANNEX XVI DEVICES

Commission Implementing Regulation (EU) 2023/1194 of 20 June 2023 amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council is published. In accordance with this implementing regulation, 31 December 2029 is the end of the transition period for Annex XVI products which require a clinical investigation. With regards to notified body agreements, the deadline to have a written agreement in place with a notified body for these products is 1 January 2028. Annex XVI products that do not require a clinical investigation, the end of the transition period is 31 December 2028. With regards to notified body agreements, the deadline to have a written agreement in place with a notified body for these products is 1 January 2027. MCA shall take into consideration these requirements for Annex XVI products during conformity assessment activities.

## 11. SIGNATURE METHODS

Signatures are required for any signed documents and records in the documentation. Signatures can be handled as follows:

- Documents may be digitally signed (e-signature).
- Signature pages can be scanned in and inserted into the electronic document.
- The relevant documents and records can be signed with a wet signature by authorized personnel.

All documents and records that require approval, such as reports, protocols, etc., except for the Declaration of Conformity, shall have approvals.

**11.1.** The company shall accept following the requirements presented by MCA through e-mails, together with both signed and unsigned documents, if provided within an email. The company shall also be responsible for the content provided within e-mails, together with signed and unsigned documents provided within the company's e-mails. These include the documents provided by the company through file-sharing platforms. If not explicitly stated, MCA shall consider all submitted documents as controlled copies.

**11.2.** As an alternative way of signing documents, MCA may use e-signature software modules to sign its documents, as well as require the company to sign documents by using these platforms. The company shall accept the usage of these platforms and shall accept the same legal responsibility as the other conventional signature types. MCA may require the company to enter data or submit documents to its digital software platforms. The company shall accept full responsibility for the data and documents provided within these platforms.

## 12. STRUCTURED DIALOGUE WITH A COMPANY

**12.1.** The structured dialogue is designed to ensure effective communication between the company and MCA during the conformity assessment pre-application, post-application, and relevant processes under the MDR.

This dialogue facilitates the flow of information between the company and MCA, addressing questions and requirements met during the application and assessment stages. As stated in the MDCG 2019-6 Rev.5 and MDCG 2022-14 guidance documents, the aim is to increase the effectiveness and predictability of the conformity assessment process.

**12.2.** The structured dialogue process shall not include consultancy. The main purpose of structured dialogue is to clarify requirements, but not the solutions. The company is ultimately responsible for fulfilling the requirements; therefore, the outputs of the structure dialogue cannot be the basis of the assessment.

**12.3.** In order to request a structured dialogue, the manufacturer shall first review MDR, other relevant guidelines, and documents published by MCA to verify if the questions have clear answers for the relevant topics.

If there is no clear answer, the manufacturer shall comply with the request and reach out to MCA by using the "Structured Dialogue Application Form and Meeting Minutes". The completed form shall be sent to [mdsales@maltaca.com](mailto:mdsales@maltaca.com) or the relevant head of audit team's e-mail address.

**12.4.** "Structured Dialogue Application Form and Meeting Minutes" is published on MCA's web page.

**12.5.** The company is responsible for providing all necessary information correctly and comprehensively, while MCA reviews this information and follows the necessary steps for the conformity assessment. In the framework of the structured dialogue, the manufacturer's questions shall adhere to the MCA's principles of independence, objectivity, and impartiality. This means that questions shall be specific rather than open-ended and shall not seek guidance on "how to comply," thereby preventing any consultancy services from being provided.

**12.6.** In which scopes structured dialogue can be conducted during the pre-application and post-application phases of the MCA, and in which scopes it shall not be conducted are defined in the Structured Dialogue Application Form and Meeting Minutes.

**12.7.** After executing the meeting, the manufacturer shall compile the summary of responses and meeting minutes on the "Structured Dialogue Application Form and Meeting Minutes", and MCA shall approve the meeting result.