MEDICAL DEVICES GENERAL TERMS

In this text,

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

General Terms for Medical Devices constitutes an inseparable part of agreements and MCA is entitled to update this document when it considers necessary. If the General Terms for Medical Devices is updated and there occurs any difference 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. General Terms for Medical Devices shall be available at www.maltaca.com.

The General Terms for Medical Devices defines the conformity assessment activities based on a quality management system and on assessment of technical documentation regarding to Annex IX - Chapter I and Chapter II 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 to the Regulation (EU) 2017/745 concerning Medical Devices shall be filed in writing along with an application form. Verbal applications shall not be accepted. The company must fill in and sign the application forms completely. The documents required in the application form must be delivered 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.

Application shall be made by authorised person of the applicant company. Application forms should be filled out by authorized person of the company.

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

1.1.2. MCA shall initiate the application review process upon receiving the application documents. It may demand the company to provide additional documents other than those specified in the application form during this process. MCA may consult to Malta Medicines Authority or competent authorities of other Member States during the process of application assessment.

1.1.3. MCA may contact the previous Notified Body or Certification Body of the company or demand the company to 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 must perform the financial obligations provided in the agreement and deliver all the documentation including specifically the Technical Documentation and Quality Management System Documentation to MCA within maximum 10 business days.

1.1.7. As for transfer applications, MCA may demand the company and the previous notified body to 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 delivered by the company shall be reviewed and missing documents, if any, shall be determined and notified to the company. The company must deliver the missing documents within maximum 10 business days. 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 demanded to provide additional information and an application shall be filed to 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 authorised 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 to 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 filed, agreements shall be signed and the requirements of the agreements shall be fulfilled at least 12 months earlier than the expiry date of the certificates, If the application date is less than 12 months before the expiry date MCA may refuse the application after the evaluation of the application however if such application is accepted the Company shall accept the deadline limitations for the non-conformity corrections found during the re-certification as well as possible waiting periods for authority consultations.

1.2. Document Submission Method During Application and Document Format

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 MCA 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 application (including test results) shall be in English language.

As a general principle, if any of the information requested in some part of technical documentation is not available in English, manufacturer should either provide translations or provide supplementary summary reports with translations of relevant information/sections or in cases where the information/reports are data heavy (or mainly graphical in nature) with very few words, Manufacturer may annotate English translations of relevant words within the reports.

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

1.2.3. File names of Technical Documentation should be reflected the information covered within that part and documents.

1.2.4. Signatures are required for any signed document in the documentation. Signatures can be handled as below:

- Documents may be digitally signed.
- Signature pages can be scanned in and inserted into the electronic document.
- All documents which require approval such as reports, protocols, etc except for the Declaration of Conformity, must have approvals.

2. Technical Documentation Pre-Reviews

Initial assessments of the Regulation (EU) 2017/745 starts with technical documentation pre-reviews. At this stage the technical documentation is assessed in a limited duration to check if proper documentation is available to start assessment processes and audits. The findings that are reported in this stage shall be closed within maximum 6 months.

3. Audits

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

3.2. Audits also cover the company's own rules for certain applied scope.

3.3. Audits shall be performed according to MCA procedures. Sampling method shall be used for audits.

3.4. Any nonconformity revealed in the audits shall be recorded by means of FR.MED.52 Finding Report. As part of the audits, the technical files prepared in line with the Regulation (EU) 2017/745 may be reviewed.

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

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

3.6.1. Under normal conditions, the period granted for correcting nonconformities shall be maximum 3 month. If the company requests the relevant period to be extended with justifiable reasons, MCA may determine to extend the relevant period. It should 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-conformities the client shall have downgraded all major non-conformities to minor level within 3 months.

3.6.2. Conformity assessment activities documentation shall be in English Language. In case of different languages are spoken or some part of QMS documentation is not available in English in audits following actions shall be applied;
- A translator shall be used in the audits. In this situation, before assignment, FR.275 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 client, that member can perform the audit without a translator.

3.7. Stage 1 Audits

3.7.1. 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.

3.7.2. Stage 1 audits shall be performed on site. MCA shall determine which audits shall be performed on site and which ones shall be performed off-site according to the rules defined in the procedures. MCA audit team may demand the company to ensure conference call and provide video, images, etc. documents during the audits to be performed off-site.

3.7.3. If minor nonconformities are detected during stage 1 audits, those nonconformities shall be checked during stage 2 audits.

3.7.4. If major nonconformities are detected during stage 1 audits, the company must correct those nonconformities and provide the evidence documentation to MCA. If the nonconformities that are detected 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.

3.8. Stage 2 Audits

3.8.1. 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.

3.8.2. The company must deliver to MCA the corrective and preventive actions for all nonconformities determined during stage 2 audits.

3.9. Surveillance Audits

3.9.1. 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 (EU) 2017/745 Regulation 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.

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

3.9.3. The first surveillance audit shall be performed in maximum 12 months after the certification date. Other following routine surveillance audits shall be performed in maximum 12 months after the previous surveillance audit however MCA may choose to perform early surveillance audits.

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

3.10.Re-Certification Audits

3.10.1. 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.

3.10.2. All the necessary sections must be audited under those audits.

3.10.3. The period granted for correction of the nonconformities under this audit may be up to 15 business days before expiration date of the certification at a maximum if it is less than 4 months before the expiration of the certification.

3.11.Transfer Audits

3.11.1. 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.

3.11.2. The company must provide to MCA the evidence of the corrective actions for all nonconformities independently from the nonconformity categories in transfer audits.

3.12. Scope Extension Audits

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

3.12.2. New agreements must be executed for scope extensions.

3.13. Change Audits

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

3.14. Unannounced Site Audits

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

3.14.2. Unannounced site audit is only a part of (EU) 2017/745 Regulation Product Conformity Assessments.

3.14.3. The company shall not be informed of unannounced site audits.

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

3.14.5. 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 must execute agreements with critical suppliers about unannounced site audits.

3.14.6. Under unannounced site audits, samples may be taken from the company or market and tests may be performed either by using company's existing capabilities or by using 3rd Party test laboratories.

3.14.7. 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.

3.14.8. The company shall inform MCA for shut down periods and non-manufacture dates for all applicable sites including the ones for critical suppliers. If the unannounced site audit team cannot reach to the site out of these periods the unannounced site audit fee and auditor expenses will still be invoiced to the company.

3.15. Critical Supplier Audits

3.15.1. 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.

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

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

3.16. Follow-up Audits

3.16.1. Follow-up audits refer to assessment of 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.

3.16.2. The decision for a follow-up audit may be made for not only routine audits but also as certaining 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 checking vigilance system and post market surveillance data.

3.16.3. Even if the audit team does not recommend for any follow-up audit, MCA certification committee may decide to perform follow-up audit for checking the nonconformity conditions.

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

4. Technical Documentation Reviews

4.1.1. One of the product conformity assessment processes under The Regulation (EU) 2017/745 is the review of Technical Documentations.

4.1.2. Clinical assessment is included in the scope of Technical Documentation review activities.

4.1.3. Technical documentation review 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 Documentations.

4.1.4. Technical Documentation review activities may be performed at the office or partly on site.

4.1.5. Technical Documentation review activities may be performed before or after the site audits. MCA may demand the Technical Documentation review nonconformities to be united with the nonconformities determined at site audits in case of necessity.

5. Processes after Nonconformity Report

5.1.1. The nonconformities determined by MCA must be documented by means of FR.MED.52 Finding Report which shall be signed mutually. This form shall be binding even if it is not signed by the company but the company may file a written objection to the nonconformities that are determined.

5.1.2. Based on the finding reports, the company must fill in FR.MED.53 Nonconformity Follow-up Form and deliver it to MCA within maximum 15 business 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.

5.1.3. FR.MED.53 Nonconformity Form provided by the company shall be assessed by MCA audit team as a result of which either it shall be approved or correction shall be demanded.

5.1.4. The company shall perform the corrective actions and corrections with due regard for the activities and durations available in the duly approved FR.MED.53 Nonconformity Follow-up Form.

5.1.5. In case the closing of corrective actions is required to be approved by MCA, the company shall deliver the evidence of corrective actions to MCA. The corrective actions shall be assessed by as a result of which they shall be either approved or rejected.

6. Certification Committee

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

6.1.2. 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.

6.1.3. The certification committee may make decisions for suspending and reinstating and withdrawal of certificates in case of critical nonconformities requiring technical assessment and following the control of the nonconformities.

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

6.1.5. Committee members make a decision within the framework of the matters stated below;

- based on the assessment documentation and additional information available, whether the requirements of (EU) 2017/745 Regulation 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 (EU) 2017/745 Regulation such as consultation procedures are performed correctly,

7. Issuing Certificates

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

7.2. MCA issue a certificate or certificates in accordance with the minimum requirements laid down in Annex XII 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 issue a certificate or certificates for the company alone and shall not issue certificates covering multiple entities.

7.3. The certificates that are issued and information about their validity shall be published on www.maltaca.com

7.4. All the details about the (EU) 2017/745 Regulation certificates shall be disclosed to Competent Authority. Certificates shall be entered electronic system referred to in Article 57 of (EU) 2017/745 Regulation.

7.5. 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 a legislation.

7.6. Certificates shall be drawn up in English languages. MCA shall issue validity of certificates as 5 years.

7.7. Each certificate shall refer to only one conformity assessment procedure.

7.8. Certificates shall only be issued to one manufacturer. The name and address of the manufacturer included in the certificate shall be the same as that registered in the electronic system referred to in Article 30 of (EU) 2017/745 Regulation.

7.9. 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 procedure, risk classification and the Basic UDI-DI as referred to in Article 27(6) 30 of (EU) 2017/745 Regulation.

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, for class IIb devices, the intended purpose.

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

7.11 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.

7.12 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 audit by the MCA of the quality management system was limited to the aspects required under that paragraph.

7.13 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.

8 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, general terms for medical devices 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 basis for suspension according to project risks.

8.1 Suspension of Certificates

8.1.1 MCA may suspend the issued certificates when the following conditions are applicable:

- Failure to deliver an action plan for the nonconformities determined as a result of the Audits and File 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 functionality of 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,
- The vigilance system records, recall decisions, warning cases, critical findings and notifications of Malta Medicines Authority and other competent authorities related products, critical post market surveillance findings related products,
- Discrepancy between the information declared in the Technical Documentation and practice,
- Failure of the company to authorize MCA staff to visit all the sites in all audits including unannounced site audits in addition to restricting access to documentation, preventing the staff from conducting detailed queries, abandoning the staff, failing to take sufficient safety measures for the staff, keeping the staff waiting for a long time, applying pressure on the staff, threatening the staff,
- 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.

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

8.1.3 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.

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

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

8.2 Withdrawing or Restricting the Scope of Certificates

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

8.2.2 MCA may withdraw the certificates when the following conditions are applicable:

- Failure of the company to perform its financial obligations,
- Determination of the fact that the company repeatedly commits the mistakes leading to suspension,
- Failure of the company to perform sufficient and effective correction for the suspended certificates during the period of suspension,
- Violation of the contractual terms by the company,
- If the company declares that it shall not observe any requirement,
- If the company demands withdrawal of the certificate of its own accord,
- If the company gives incorrect 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 and other competent authorities related public health and safety, critical post market surveillance findings related products.

8.2.3 In below cases, the certificates issued may be directly withdrawn without a suspension period. In any case the certification committee based on the criticality of the act or violation, shall give the final decision.

- Repeating same major non-conformities which requires suspension
- Repeating failures to the contractual obligations
- Direct violation to the contract terms.
- Obvious intentional acts which compromise product safety and performance
- Providing falsified information
- Declaring acts that disallow MCA to execute conformity assessment tasks.
- Obvious intentional acts which may decrease the reputation of MCA.
- Repeating suspension reasons
- Upon request of the manufacturer

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

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

9 Rights and Obligations of MCA

9.1 MCA and all the employees shall keep confidential all kinds of written and verbal 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 circumstance. Nevertheless, the information may be disclosed to the Competent Authority, Authorities Responsible for notified bodies 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.

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

9.3 MCA has executed Impartiality and Non-Disclosure Agreements with its employees as part of its duty of impartiality and non-disclosure.

9.4 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.

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

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

9.7 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 delivered 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.

9.8 MCA undertakes to comply with the documentation of the Competent Authority, Authorities Responsible for notified bodies and European Commission concerning notified bodies and certification bodies in addition to the abovementioned requirements.

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

9.10 MCA may cancel the agreement in case the company fails to fulfil any contractual obligation.

9.11 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 file review.

9.12 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.

9.13 MCA may subcontract the product conformity assessment processes partially if it deems necessary. The details of the activities to be subcontracted and the

subcontractor shall be shared with the company and unless any objection is made within 5 business days, the subcontractor shall be considered to have been accepted by the company. Even in case of subcontracted activities, MCA shall remain responsible for the certification decision as well as all the relevant activities.

9.14 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 unilaterally. MCA will publish current available fees in www.maltaca.com.

9.15 If the company wishes to cancel the agreement during the performance of any service including office 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.

9.16 If the company make request to transfer of 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 validity period of certificates, which one is earlier. MCA shall submit all relevant documentation to Incoming Notified Body. In this situation it shall be possible to issue an invoice to the company as abovementioned.

9.17 It may demand the company to recall products in case of any effect on public health and product and patient safety.

9.18 It may conduct extra office review, follow-up audit or unannounced site audit according to the findings determined through the internal audits of MCA, European Commission, Competent Authority and Authorities Responsible for notified bodies audits.

9.19 MCA may cancel the agreement unless the company provides the necessary documentation within 10 business days as from the signature of the agreement.

9.20 MCA may demand interpreter or all kinds of document translation incase of the assessment team including the committee members does not know the local language of the company.

9.21 MCA shall keep all documentation which needs to be upload to EUDAMED, according to PR.02 Procedure, until EUDAMED is fully functional. When EUDAMED becomes functional, all necessary documentation shall be uploaded to the EUDAMED database by Competent Authority Coordinator according to PR.MED.06 Procedure.
If Malta Medicines Authority 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.

9.22 Surveillance activities and post-certification monitoring
MCA 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 measure related situations
— where necessary, impose specific restrictions on the relevant certificate, or suspend or withdraw.

9.23 If MCA decides to cease its activities, it shall inform the Malta Medicines Authority and the certified manufacturers as soon as possible and not later than one year before ceasing its activities. MCA shall first communicate with Malta Medicines Authority for the period that 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 nine 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.
9.24 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.

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10 Rights and Obligations of the Company

10.1 The company must provide correct information during the entire assessment process including application and accept all the sanctions that shall arise from failure to fulfil this obligation.

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

10.3 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, make 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.

10.4 Observers, guides and candidate auditors/experts may accompany MCA in the audits or unannounced site audits it shall perform on the site or office of the company. An observer may either be any person that observes a member of the audit team or else a representative of the customer or the Authorities Responsible for notified bodies 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, witness 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.

10.5 The company shall be obliged to provide all kinds of written and verbal information required for the audit to the relevant people including MCA staff and ministerial representatives.

10.6 The company must submit plans for changes that can effect MCA's audit and technical documentation review tasks, data presented on the certificates and contracts, data used for MCA's planning activities, legal changes, critical staff 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. 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 FR.MED.51 Change notification Form available in www.maltaca.com. This form may include some examples for changes to be reported but it should be noted that the items listed in FR.MED.51 is not exhaustive and changes which may not fall in defined types shall be reported as selecting "other" in this form. If the company is not sure whether a change need to be reported to MCA or not, it shall report anyway.
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 staff,
- 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 specific procedures of the Regulation (EU) 2017/745.

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

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

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

10.9 The company shall be obliged to deliver the Technical Documentation in executed, approved and controlled copy to MCA. This rule shall apply to the documentation to be submitted in digital media. All of the documentation to be delivered shall be in English.

10.10 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 the certificate unless otherwise specified in the relevant directive or legal regulation.

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

10.12 MCA may conduct additional audits for a certain charge when required for evaluating the impact of the changes on the system or product.

10.13 The company must 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.

10.14 The company shall be obliged to comply with the Certificate and Brand Usage Procedure, Certification Procedure, this text (General Terms for Medical Devices) and similar MCA instructions and procedures of which updated versions are available at www.maltaca.com and keep up with their updated versions.

10.15 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.

10.16 The company shall be obliged to discontinue using MCA brand and notified 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.

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

10.18 If the company makes an appeal as provided in PR.04 Assessment of Complaints and Appeals Procedure and it does not accept (get satisfied with) the decision rendered by the objection committee, the company may file an application to the relevant authority. If MCA is in excess of the period granted for resolving the objection as indicated in PR.04, the company may file an application to the relevant legal authority in the same manner. The company may file an objection to any decision rendered by MCA in relation to the company within 10 business days. The company shall be responsible for covering the cost of the relevant committee, experts and similar other costs to be incurred in relation to the objections and complaints.

10.19 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 the Regulation (EU) 2017/745.

10.20 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, it must indicate the justifications for the invalidity.

10.21 The company shall be obliged to inform MCA of the reason for rejection if any of its applications has 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).

10.22 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.

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

10.24 The company must agree that the agreement that is duly signed shall not be construed as entitlement for the certificate.

10.25 The company accept and make payment for the invoices issued by MCA for the duly completed services even if the result is negative.

10.26 The company must pay for the services which have been previously performed in case the agreement is terminated for any reason.

10.27 The company must serve a written notice if it intends to terminate the agreement.

10.28 The company must make timely payments.

10.29 The company must 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.

10.30 The company must submit all the declarations and documents required by MCA within maximum 10 business days if the company intends to transfer any certificate issued by MCA to another notified body.

10.31 If the company intends to transfer any certificate issued by another notified body to MCA, it must submit the documents required by MCA within maximum 10 business days. In case of any such certificate transfer demand, it must accept that MCA may contact the existing notified body. It must also agree that MCA may cancel the agreement during application assessment stage according to the information given by the notified body. If the notified body does not give any response within maximum 15 business days, MCA may suspend certificate transfer process.

10.32 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 transfer assessment. The company must cover the cost of the relevant committee, experts and similar other costs to be incurred in relation to the transfer assessment.

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

10.34 The company must not implement any substantial changes without receiving consent from MCA.

10.35 The company must complete the visa invitation form to be provided in 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.

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

10.37 The company must allow MCA staff to make intensive and detailed questioning in case of necessity.

10.38 The company must agree to and allow all the audits to be conducted by MCA at the site of the company including unannounced site audits.

10.39 The company must 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.

10.40 The company must make agreements with suppliers and subcontractors in order to ensure that all kinds of audits, including unannounced site audits and witness audits, might 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 must accept the sanctions to be applicable in case the critical suppliers and subcontractors do not give consent to such audits.

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

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

10.43 The company must ensure that necessary information is given and necessary measures are taken for protecting the safety and health of the staff assigned by

MCA as well as the accompanying employees. The necessary equipment must be provided by the company.

10.44 The company must agree that MCA shall not be responsible for any loss to be incurred as a result of the termination of Notification of MCA and must not make any demands for those reasons.

10.45 The company must not file application to more than one Notified Body for the same products simultaneously.

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

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

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

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

10.50 The company must 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.

10.51 The company must not undertake manufacture and sales of products with CE marking when the certificate is subject to suspension and withdrawal or its validity period has expired.

10.52 The company must not use CE marking for products not certified by MCA.

10.53 The company must accept the findings of the extra office review, committee revew, 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 in defined due time.

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

10.55 MCA will not make any refund in case of delay of a responsibility of the client more than 7 days such as technical documentation sending, nonconformity closure etc and having caused at least one delay more than 7 days in any responsibility while carrying out the projects which may cause MCA not to be able to allocate efficient resource planning and effective assessment.

10.56 The company must create all applicable documents according to (EU) 2017/745 Regulation, regardless of whether EUDAMED is functional in whole or in part, and submit them to MCA. Once EUDAMED is actively working, all necessary documents must upload to the EUDAMED.

10.57 When complying with imposed deadlines the company must consider availability of MCA resources and time needed for planning. The company shall not make MCA responsible for inability to allocate necessary resources when the response is provided closer to the ending deadlines and which may effect the validity of the certificates. The company shall be responsible to communicate and confirm with MCA to check time needed for resource allocation and planning when considering the response time.

10.58. Transition requirements in accordance to the (EU) 2023/707 Ammending Regulation

Where a company certified by 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 to the Article 120 (3c) (EU) 2017/745 Regulation, 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.

10.58.1. 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.

10.58.2. The surveillance assessment transfer application of the manufacturer shall be received by the Sales Unit with the FR.MED.01 Annex 4-Information Related to Transfer of Surveillance Assessments Form and approved proof documents requested in this annex until 26 May 2024 and that 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 "Manufacturer Declaration" shall be requested from the manufacturer.

10.58.3 After the necessary documents are completed, planning is made according to the PR.MED.25 Medical Devices Audit and File Review Planning Procedure, and the final decision on the appropriateness of the transfer shall be made according to the PR.MED.27 Medical Devices Product Conformity Assessment Procedure. .

10.58.4. When necessary, approvals are obtained, Sales Unit shall document FR.MED.02 93/42/EEC Product Conformity Assessment Agreement, FR.MED.63 General Conditions Terms and FR.MED.202 Transfer Agreement For Surveillance Of Legacy Devices and FR.MED.65 Duration and Fee Calculation Form.

10.58.5. In accordance to the 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 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.

10.58.6. 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.

10.58.7. 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.

10.58.8. No later than 26 September 2024, MCA that has signed the written agreement referred to in Article 6(e), 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.

10.58.9. 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 MDD Notified Body.

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

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

10.59. 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 to 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.