## PARTIES

This (EU) 2017/745 Regulation Product Conformity Assessment Agreement (the “Agreement”) is entered into by and between  located at the address of “”with its e-mail address being “”, telephone number “” and facsimile number “” (to be hereinafter referred to as the “**Company**”) and “**Malta Conformity Assessment Ltd.** located in “**Malta Life Sciences Park Sir Temi Zammit Buildings San Gwann SGN 3000 Office LS2.1.11, Malta**” with its telephone number being “**---**” and facsimile number “**---**” (to be hereinafter referred to as “**MCA**”).

## DEFINITIONS

**Notified Body**: The entity assigned by the designation authorities to undertake product conformity assessment activities under (EU) 2017/745 Regulation.

**Product Conformity Assessment**: The process demonstrating whether the requirements of (EU) 2017/745 Regulation relating to a device have been fulfilled. Control of product conformity with the conditions provided in the Regulation (EU) 2017/745 by means of application review, documentation reviews, Technical Documentation reviews, audits, evaluation, decision and similar activities.

**Certificates**: EU Certificates issued under the Regulation (EU) 2017/745.

**Authorities Responsible for Notified Bodies:** The authorities in charge of assigning/designating Notified Bodies (Malta Medicines Authority in Malta.)

**Competent Authority:** Regulatory authority of the country responsible for medical devices.

**Medicinal Products Authority:** Competent Authority assigned for 2001/83/EC Directive.

**Sampling Method:** Assessment of the efficiency of any quality assurance system and documentation by means of reviewing implementation samples. This method is not based on reviewing all the documentation and files. The frequency of sampling may change.

**PSUR:** Periodic safety update report

**SSCP:** Summary of safety and clinical performance

**EUDAMED:** Electronic System implemented by EU Commission.

**Company:** A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark. Synonymously used for the term manufacturer in (EU) 2017/745

## SCOPE

This agreement defines the terms and conditions binding on the Company and MCA with respect to the product conformity assessment services specified in article 3.1 under (EU) 2017/745 Regulation. “**Medical Devices General Terms**” issued by MCA is an inseparable part of this agreement and the Company shall be liable for conforming to the medical devices general terms including any amendments thereof unless the agreement is terminated. The Company shall be responsible for keeping up with the “Medical Devices General Terms”. The Company shall be obliged to keep up with the amendments introduced to the text.

## SERVICES

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Service Type** | **Product Conformity Assessment Method** | **Product/Product Group Name** | **Product Class** | **Certificate Number\*** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

\* Certificate number shall be indicated for services requiring any alteration in the existing certificates of the company.

## PAYMENTS

## 4.1. INITIAL ASSESSMENT /RE-ASSESSMENT /SCOPE EXTENSION /TRANSFER ASSESSMENT /CHANGE ASSESSMENT

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** | |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2. SURVEILLANCE ASSESSMENTS (PER EACH)

(Normally the number of surveillance assessments to be performed within 5 years of certificate validity is four(4) however MCA may increase the number of surveillance audits to be performed based on compliance level of the company. If this part left empty, the fees for surveillance assessment in the previous agreement remains valid, if not these fees replace the older surveillance fees.)

## 4.2.1 SURVEILLANCE 1

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** | |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2.2 SURVEILLANCE 2

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** | |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2.3 SURVEILLANCE 3

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** | |
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|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.2.4 SURVEILLANCE 4

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Duration** (man/day) | **Fees** | |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Total** |  |  |

## 4.3. UNANNOUNCED AUDITS

(If this part left empty, the fees for unannounced audit in the previous agreement remains valid, if not these fees replace the older surveillance fees.)

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Duration** (man/day) | **Total Fee** | |
|  |  |  |  |

## 4.4. PAYMENT OBLIGATIONS

1. Prices do not include VAT. For each portion of the payment the VAT shall be included in the transfer.
2. Transportation and accommodation costs of MCA employees, including the ones under observation or training, are not included in the prices indicated above and they shall be invoiced separately and shall be paid by the company within maximum 10 business days. Economy class (including seat selection, baggage, extra legroom) shall be preferred for flight tickets provided that MCA reserves the right to demand “business” class tickets for flights over 7 hours. 4-star and higher-level hotels shall be preferred for accommodation. MCA may request special transportation and accommodation alternatives in case any of its employees has a specific medical condition.
3. Where travelling is necessary for the conformance of the tasks, the Company shall pay fifty Euro (50 EUR) travel fee per hour. The time spent on travel is calculated for each individual traveling for conformity assessment tasks.
4. The Company shall pay 50% of the total initial assessment fee and/or transfer fee in advance within maximum 10 business days upon the signature of the agreement. MCA shall not begin to perform its contractual obligations unless this payment is duly made.
5. The remaining portion of the initial assessment and/or fee shall be paid by the company in advance within maximum 10 business days after the completion of the activities for the assessment of product conformity.
6. Total surveillance fee shall be paid by the company in advance 30 days before the scheduled surveillance audit date at the latest. The costs incurred for the surveillance audits shall be invoiced separately.
7. The prices and costs of unannounced site audits shall be paid by the company within maximum 10 business days after the unannounced site audit is conducted.
8. The cost of tests to be performed/contracted under unannounced site audits as well as the cost of the sample received from the market shall be invoiced separately to be paid by the company within maximum 10 business days after the unannounced audit.
9. Scope extension assessment and change assessment fees shall be arranged through a separate agreement and paid by the company in advance within maximum 10 business days following the signature of the agreement. The Assessments shall not be scheduled and certificates shall not be extended before the payment is made.
10. Follow-up audit fees shall be invoiced separately. The relevant shall be paid by the company in advance within maximum 10 business days after the invoice is issued. The audits shall not be scheduled before the payment is made.
11. Annual Certificate Usage Fee shall be paid once the certification is performed and shall not be refunded once it is paid even if the certificates are withdrawn.
12. Any dispute between the company and the notified body concerned, arising from the application of Annex VIII (such as implementation of classification rules or qualification of the product etc.) of the Regulation (EU) 2017/745, shall be referred for a decision to the competent authority in which the company has its registered place of business. 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. All of the costs arising from such referral shall be paid by the company.
13. For several devices, consultation to the authorities is necessary. The consultation fees required from the applied authority is not included in the prices and will be invoiced separately. For the tasks to be performed for preparation to the consultation and if the feedback from the consultation requires changes in the assessments and additional documents, explanations, revision for client files are required and in case of an additional time spent on repeating consultations or follow-up, a fee of one hundred euro (100 EUR) will be charged per working hour and this will separately be invoiced to the company.
14. The company shall be responsible for the payments of the planning costs and expenses in case of a request by the company for changing the agreed audit dates.
15. The above prices include one (1) time review for non-conformity corrections. MCA will invoice three hundred and fifty Euro (350 EUR) for the time spent on each additional reviews for each remaining non-conformity within allowed timeline for non-conformity corrections.
16. MCA will invoice hundred and fifty Euro (150 EUR) for administrative work for controlling the completeness of change assessment submissions.
17. MCA will invoice five hundred Euro (500 EUR) for administrative work in case of a transfer from MCA to another notified body.
18. The company shall inform MCA for annual shut downs and non-manufacture periods for all applicable sites including the ones for critical suppliers. If the unannounced audit team cannot reach to the site out of these periods the total unannounced audit fee and auditor expenses will be invoiced to the company.
19. MCA will invoice one hundred Euro (100 EUR) for per working hour in case of the company will submit an appeal to the decisions taken on certification.

**4.5. DURATION CRITERIA**

|  |  |
| --- | --- |
| Effective Number of Employees |  |
| Other |  |

## RIGHTS AND OBLIGATIONS

## RIGHTS AND OBLIGATIONS OF MCA

1. MCA shall perform the product conformity assessment services for the products specified in article 3 in line with the methods and rules indicated in MCA procedures and Medical Devices General Terms and it shall report the results accordingly. Conformity assessment activities shall be conducted with due regard for the principles of impartiality and confidentiality specified by MCA and the company information shall not be disclosed to third parties except to the Competent Authorities, Authorities Responsible for Notified Bodies, European Commission, courts or required by law.
2. MCA shall ensure that its personnel, committees, subsidiaries, subcontractors, any associated body or personnel of external bodies respect the confidentiality of the information and paying attention to the principles of impartiality while conducting conformity assessment activities, except to the Competent Authorities, Authorities Responsible for Notified Bodies, European Commission, courts and required by law. Reporting activities shall be conducted based on objective findings and sampling methods and EU Certificates shall be issued according to the type of application incase of a positive product conformity assessment result. In case of issuance of certificates, their validity and scope shall be published on [www.maltaca.com](http://www.maltaca.com). Upon the termination of the notification of MCA, the company shall be served a written notification to provide the necessary information about the transfer to another Notified Body. The appeals and complaints referred by the company shall be evaluated and the company shall be informed of their outcome.
3. MCA shall be entitled to revoke this agreement and the previously issued certificates if the company fails to perform any of its contractual obligations. If it is discovered that the information provided in the application file has been subject to any change at the end of the application review or during the file review, it may alter the conditions of this agreement and reserves the right to revoke this agreement. If the audits reveal any information different from the one indicated in the application for such as the number of employees, product scope, sites, and critical suppliers, MCA shall be entitled to alter the audit periods and fees and suspend the audit according to its procedures.
4. MCA shall ensure that company submit for prior approval plans for substantial changes to the quality management system, or the device-range covered and relevant information relating to such changes, assess the changes proposed and verify whether, after these changes, the quality management system, or the design of a device or type of a device, still meets the requirements of (EU) 2017/745 Regulation, and notify the company of its decision. MCA shall determine the actions necessary to be taken and approve or reject the change subsequently. The change may require updating the agreements or collecting additional changes.
5. MCA may subcontract the product conformity assessment procedures partly in case of necessity. The details of the subcontracted activities and subcontractor shall be provided to the company which shall be deemed to have approved the subcontractor unless it poses an objection within 5 business days. Even in case of subcontracted activities, MCA shall assume responsibility for all the activities and certification decision. MCA shall make the list of subcontractors available on www.maltaca.com. MCA shall make it sure that the subcontractor does not further subcontract it’s duties to another company or person and shall fulfil the requirements of the Regulation (EU)2017/745.
6. MCA reserves the right to alter the surveillance audit fees and other prices after the signature of the agreement. The current available fees will be published in [www.maltaca.com](http://www.maltaca.com).
7. Surveillance audit fees are specified in Section 4.
8. Normally, unannounced site audits are performed minimum 1 time every 5 years however MCA may increase the frequency of unannounced site audits in case of necessity. The frequency of unannounced site audits shall be evaluated in terms of the risks having the potential to have an impact on the activities of the company. For example, withdrawal of critical personnel from their position, extremely frequent product conformity issues, extremely frequent complaints and high-risk devices may lead to increase of the frequency of unannounced site audits. Samples may be obtained from the market, company warehouse or production line in order to conduct tests under unannounced site audits. Critical suppliers of the company may be subject to unannounced site audits as well. All the costs arising from unannounced site audits must be paid by the company. In order to give approval for unannounced site audits in advance, the visa invitation form to be provided in the attachment of this agreement must be completed by the company which must also issue a visa invitation letter in addition to this form upon request of MCA.
9. MCA may demand the company to recall any product in case of any risk for public health and product safety.
10. MCA may conduct extra office audits, surveillance audits, fallow up audits and unannounced site audits based on the findings obtained from internal controls of MCA and audits of European Commission or Competent Authority.
11. MCA reserves the right to suspend the certificates and revoke the agreements and certificates unless the relevant nonconformity is resolved until the specified deadline. MCA does not have any obligation to remind the company of the expiration of the deadline specified for the resolution of the nonconformity or any other response.
12. MCA reserves the right to include observers, auditor under observation or training to the audits and other relevant conformity assessment tasks to be performed for the company.

## RIGHTS AND OBLIGATIONS OF THE COMPANY

1. The Company must provide correct information during the entire product conformity assessment process including specifically the application and agree to be bound by all the sanctions to arise from failure in performing this obligation. It must provide all the documentation including the Technical Documentation and quality management system documentation to MCA within maximum 10 business days. The company must fulfil its financial obligations within the deadlines specified herein. The company must agree that execution of the agreement should not be construed as an entitlement to the certificate and pay the prices for all the services that are conducted even if the process results negatively. The cancellation of the agreement shall not eliminate the obligation to pay for the services that have been already performed.
2. The Company must sign the Transfer Agreement without any financial value based on the recommendation of MCA or must provide an agreement which covers the required information in Transfer Agreement in case of any request to transfer a certificate issued by MCA to another notified body. In that case, all the declarations and documents demanded by MCA must be delivered to MCA within maximum 10 business days.
3. The Company must deliver all the documents demanded by MCA within maximum 10 business days if it intends to transfer the certificates issued by another notified body to MCA. In case of any such certificate transfer request, it is agreed that MCA may contact the existing notified body of the company. MCA reserves the right to revoke the agreement during application review phase according to the information to be given by that notified body or in case of lack of any such information.
4. The company must submit 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, the approved type of a 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 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.
5. The company shall be obliged to inform MCA of vigilance system records, recall decisions, warning cases, findings of competent authorities, and critical after-sales surveillance findings within maximum 1 business days. MCA may conduct unannounced site audits and planned audits to inquire into the notifications.
6. The company shall not demand consultancy services from MCA in any manner. MCA employees shall be entitled to visit all the sites including design, manufacture, storage, testing and examination sites, ask questions to employees working on those sites, examine the products and documents at all sites, receive samples from manufacture and storage sites and bear witness in testing processes. MCA may conduct deep and detailed inquiries during audits in case of necessity. The company must make cooperation in order to enable MCA employees to conduct the audits. In that respect, MCA may suspend the audit and reserves the right to revoke the agreement in case of any condition damaging the order of the audit such as failure in answering questions in a timely manner, providing the necessary documents and accompanying the auditors. The company must furnish information required for protecting the safety and health of audit staff and accompanying employees, take necessary measures and provide necessary equipment.
7. The company shall enable MCA to conduct planned or unannounced witness audits along with the staff of European Commission, Authorities responsible for Notified Bodies, and Competent Authorities. In order to visit critical suppliers as part of the audits, the company must sign agreements with its suppliers providing that employees of MCA, European Commission, Authorities responsible for Notified Bodies and Competent authorities may conduct planned or unannounced site audits at the sites of suppliers.
8. The company shall fulfill obligations for providing PSUR and SSCP in defined timelines to both MCA and EUDAMED if it is required by the (EU)2017/745 Regulation.
9. The Company shall be obliged to use CE mark and MCA trademark correctly. CE mark shall not be attached to the products and such products may not be marketed so long as the certificates are suspended and invalid. CE mark may only be attached to products succeeding in conformity assessments conducted by MCA. The Company may not place the products certified by MCA into the market with the number of another notified body after the certification date.
10. In the event that the accreditation or notification of MCA is terminated for any reason after the signature of this agreement, the company may not make claims from MCA in any manner including for pecuniary and non-pecuniary losses such as loss of revenue, investment costs etc. The parties irrevocably agree and acknowledge this condition mutually with their freewill.
11. The Company shall inform MCA of any change in its address and contact details.
12. The Company shall not file a parallel application to more than one Notified Body for the same products.
13. The Company must assume all the liabilities arising from cancellation or suspension of its certificates including the liabilities towards customers and must not hold MCA responsible in that regard.
14. The Company shall comply with the request of MCA to perform video conferences, telephone conversation and to supply video and photo as a part of audit.
15. The Company must completely comply with the nonconformity resolution dates declared after the assessments, monitor compliance with those dates and must not hold MCA responsible for any failure in that regard.
16. The Company may appeal to the employees assigned by MCA as well as the decisions on certification within 10 business days by providing justifications for the appeal. Besides, it may file complaints in relation to the MCA services and employees along with detailed explanations and evidence in line with the complaint and objection procedure published on [www.maltaca.com](http://www.maltaca.com). The company shall assume the expenses incurred for the experts, committee to be established for complaints and objections and similar costs.

## TRANSITION REQUIREMENTS UNDER REGULATION (EU) 2023/607

* 1. Regulation (EU) 2023/607 of the European Parliament and the Council of 15 March 2023 amending Regulations (EU) 2017/745, as regards the transitional provisions for certain medical devices, has entered into force on 20 March 2023.
  2. In line with the amendments made by Regulation (EU) 2023/607 and (EU) 2017/745 Medical Devices Regulation (MDR) Article 120 'Temporary Provisions', certificates issued under Directive 93/42/EC 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:

1. 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;
2. 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.
   1. For the devices specified in Article 6.2, the Company may place its devices on the market or put them into service until the dates referred to in points (a) and (b) of Article 6.2 only if the following conditions are fulfilled:
3. Those devices continue to comply with Directive 93/42/EEC as applicable.
4. There are no significant changes in the design and the intended purpose.
5. 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.
6. No later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with MDR Article 10(9);
7. No later than 26 May 2024, the manufacturer or the authorized representative shall lodge a formal application with a notified body assigned within the scope of the MDR for conformity assessment of the certified device or a device intended to replace this device and no later than 26 September 2024, this notified body and the manufacturer shall sign a written agreement in accordance with second subparagraph of Section 4.3 of MDR Annex VII.
   1. In surveillance assessments for devices referred to in paragraphs 6.2 (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.
   2. Until 26 September 2024, unless the company agrees with MCA that it will carry out the surveillance specified in Article 6.4, MDD Notified Body shall continue to be responsible for the necessary surveillance assessment 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. These surveillance assessments shall also include unannounced audits.
   3. No later than 26 September 2024, MCA 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.
   4. Arrangements for the transfer of surveillance from MDD Notified Body to MCA shall be clearly defined in an agreement between the Company, MCA, and MDD Notified Body where applicable.
   5. MCA shall not be responsible for the conformity assessment activities carried out by MDD Notified Body.
8. **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.

## GENERAL PROVISIONS

* 1. MCA shall not be responsible for the time spent for review of the files by competent authorities for any reason.
  2. The disputes arising from this agreement shall be subject to Malta Law.
  3. The parties must serve requests and notices for cancellation of agreements in writing.
  4. In case the company fails to perform any of the provisions herein, MCA shall reserve the right to revoke the agreement. In such a case, the certificates issued under the revoked agreements shall be revoked automatically.
  5. All (EU) 2017/745 Regulation Certificates shall have a maximum 5 years of validity period. In case of certificate transfers, the validity period of the certificate shall be limited to the certificate validity period applicable for the previous notified body. Certificate validity period may be limited accordingly in case of a revision on standards, regulations etc.
  6. The person signing this agreement must be authorized to represent the Company.
  7. The addresses specified herein are the notification address of the parties and address change must be notified to the other party in writing. Otherwise, the notices delivered to those addresses shall be deemed to have been validly served.

## ANNEXES

* 1. ANNEX-1 Medical Devices General Terms
  2. ANNEX -2 Visa Invitation Form

Date:

Agreed on behalf of Agreed on behalf of

Malta Conformity Assessment Ltd. the Company

Malta <place >

……………………… ………………………

**<name> <name>**

**General Manager <position (Authorized Person)>**