**PURPOSE AND SCOPE**

The purpose of this Standard Operating Procedure (SOP) is to define the process for CE marking medical devices placed on the market under Regulation (EU) 2017/745 also known as the Medical Device Regulations (MDR). This SOP applies to any CE marked medical device to be placed on the market by XXXXX as Legal Manufacturer.

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**ROLES AND RESPONSIBILITIES**

The table below provides a summary of roles and corresponding responsibilities included in this document.

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| **Role** | **Responsibility** |
| *Devices Regulatory* | Device determination and classification. Identification of an appropriate Conformity Assessment Procedure (regulatory compliance  strategy). |
| *Devices Regulatory Lead* | Responsible for product-specific technical documentation assembly and Conformity Assessment Procedure execution. |
| *Notified Body Representative* | XXXXX’s liaison and primary contact with the Notified Body. |
| *Executive Director Level Devices Regulatory, Quality* | Identify the Legal Manufacturing site and appoint the Authorised Representative if necessary. Identify an appropriately designated Notified Body for each product. |
| *Legal Manufacturer’s Person Responsible for Regulatory Compliance (LM-PRRC)* | Responsible for CE marking and overall conformity with Legal Manufacture’s obligations under the MDR. |
| *Authorised*  *Representative’s Person Responsible for Regulatory Compliance (AR-PRRC)* | As the Legal Manufacturer’s representative in the EU the AR-PRRC is the primary point of contact for European Competent Authorities. Acts on the Legal Manufacturer’s behalf in relation to specified tasks with regard to obligations under the MDR. |

**PROCEDURE**

1. **Activities in Preparation for a New Device**
   1. Determination and EC Product Classification
      1. Devices Regulatory determines if a proposed product qualifies as a medical device or as an accessory to a medical device in accordance with Global medical device/combination product determination process SOP-430926.
      2. If the proposed product qualifies as a medical device or an accessory to a medical device, then Devices Regulatory determines the classification according to MDR Annex VIII.
      3. Devices Regulatory records the qualification and classification using EU Medical Device Regulation Medical Device Determination Template FORM-493926.

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* 1. Legal Manufacturer/Authorised Representative Identification

NOTE: XXXXX Thousand Oaks USA is the preferred Legal Manufacturing site and XXXXX Breda The Netherlands is the preferred Authorised Representative site. Other models are possible.

* + 1. Executive Director Level (or higher) personnel from Devices Regulatory, Operations Quality, Final Product Technology Quality identify the XXXXX site to assume responsibility as Legal Manufacturer and where this site is located outside the EU, EEA or Switzerland, designates a single XXXXX site located within the EU, EEA, or Switzerland to assume responsibility as Authorised Representative for the new product.
    2. The Legal Manufacturer and Authorised Representative establish a written agreement defining their respective roles and responsibilities.
  1. Legal Manufacturer Obligations
     1. The Legal Manufacturer appoints at least one full time employee to the role of PRRC per Multisite Procedure for Appointment of Key Roles in the QMS and Development of Job Descriptions SOP-428227.
     2. The PRRC or their delegate is responsible for ensuring that:
        + CE marked devices within their scope of responsibility are designed and manufactured in accordance with the requirements of the MDR.
        + Appropriate technical documentation, declarations of conformity and relevant certificates are maintained at the disposal of the Notified Bodies and Competent Authorities for at least 10 years after the last device covered by the declaration of conformity has been placed on the market.
        + Adequate procedures are maintained to keep series production in conformity with MDR requirements.
        + Changes to device design and to harmonised standards are taken in to account in a timely manner.
        + Indelible, easily legible, clearly comprehensible information is provided to users and patients in an official language(s) determined by the Member State in which the device is made available.
        + An adequate quality system is maintained addressing requirements stated in section 2.1.2.

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* 1. Legal Manufacturing Site Obligations to the Authorised Representative Site
     1. Under the established agreement, the Legal Manufacturer must:
        + Provide the Authorised Representative site with continuous unimpeded access to technical documentation and information relevant to Vigilance.
        + Delegate authority to the AR-PRRC to distribute applicable information directly to authorities or bodies in the Community for the purpose of market surveillance.
        + Inform the AR-PRRC of substantial changes to the Quality System accredited by the Notified Body.
        + Inform the AR-PRRC of significant changes regarding the medical device design and/or technical documentation.
        + Empower the AR-PRRC to end any infringement, where a Member State establishes that the CE marking has been affixed unduly or is missing in violation of the MDR under conditions imposed by that Member State.
        + Permit unimpeded access to the Legal Manufacturer site for the purpose of inspection by Competent Authorities or Notified Bodies from the Community.
  2. Legal Manufacturer/Authorised Representative Identification

NOTE: XXXXX Thousand Oaks USA is the preferred Legal Manufacturing site and XXXXX Breda The Netherlands is the preferred Authorised Representative site. Other models are possible.

Executive Director Level (or higher) personnel from Devices Regulatory, Operations Quality, Final Product Technology Quality identify the XXXXX site to assume responsibility as Legal Manufacturer and where this site is located outside the EU, EEA or Switzerland, designates a single XXXXX site located within the EU, EEA, or Switzerland to assume responsibility as Authorised Representative for the new product.

The Legal Manufacturer and Authorised Representative establish a written agreement defining their respective roles and responsibilities.

* 1. Authorised Representative’s Obligations
     1. Under the established agreement, the Authorised Representative appoints at least one full time employee to act as PRRC per Multisite - Procedure for Appointment of Key Roles in the QMS and Development of Job Descriptions SOP-428227
     2. The AR-PRRC or their delegate:
        + Represents the Legal Manufacturer in good faith to authorities and bodies within the Community with regard to the Legal Manufacturer's obligations under the MDR.
        + Maintains compliance to the national legislation of the Member State in which the Authorised Representative is domiciled.

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* + - * Keeps the Legal Manufacturer informed in all matters that may be connected to the CE marked medical devices placed on the market in the EU and/or third countries recognizing CE marking for market access.
      * Provides documentation and information incumbent to the Legal Manufacturer that a market surveillance authority requests for the purpose of market surveillance.
      * Supports Legal Manufacturer inspections by Competent Authorities or Notified Bodies from the Community.
      * Informs the Legal Manufacturer of any infringement and the action taken to end it.
    1. The AR-PRRC may rescind the quality agreement if the Legal Manufacturer fails to provide reasonable access to the applicable information.
    2. If the Legal Manufacturer is not complying with the requirements of MDR, then the AR-PRRC must communicate this to the Legal Manufacturer.
    3. If the LM-PRRC and AR-PRRC disagree then the AR-PRRC must notify the Competent Authority and the Notified Body of the non-fulfilment of the Legal Manufacturer’s obligations causing the infringement.

1. **Requirements for Conformity Assessment**
   * 1. Conformity Assessment Procedure Selection
        1. The Devices Regulatory Lead for the specific program identifies an appropriate Conformity Assessment Procedure from options specified in MDR section 2, Article 52.
        2. The Devices Regulatory Lead documents the strategy for regulatory compliance in the Regulatory Plan, identifying:
           + Device class
           + Conformity assessment procedure
           + Economic Operators including Legal Manufacturer, Authorised Representative and Importer(s)
           + Unique device identification (UDI) device identification/production identification (DI-PI) strategy describing if and how UDI-PI codes will be applied to product labels

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* + 1. Quality Management System
       1. The Legal Manufacturer must maintain a quality management system meeting the specific requirements of the Conformity Assessment Procedure but addressing at minimum:
          - Conformity Assessment Procedure selection
          - Management Responsibility
          - Resource Management
          - Risk Management Including supplier management
          - Clinical Evaluation including Post market clinical follow-up (PMCF)
          - Product Realization
          - (UDI) assignment and verification
          - Post-market surveillance
          - Communication with Competent Authorities, Notified Bodies, other economic operators, customers and/or other stakeholders
          - Vigilance Reporting
          - Field Safety Corrective Action
          - Corrective and Preventive Action
          - Product Monitoring and Measuring
    2. Technical Documentation
       1. The Devices Regulatory Lead with assistance from other functions assembles technical documentation in accordance with SOP-428902 Preparation and Maintenance of MDR Technical Documentation.
    3. Clinical Evaluation

NOTE: Clinical Evaluation is mandatory for all medical devices. Confirmation of conformity with relevant general safety and performance requirements must be based on clinical data providing sufficient clinical evidence.

Alternatively, for class I and IIa devices, XXXXX may demonstrate conformity with general safety and performance requirements based on the results of non-clinical methods alone, including performance evaluation, bench testing and pre-clinical evaluation. In all cases the approach must be documented in accordance with SOP-427826 MDR Clinical Evaluation.

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* + 1. EUDAMED
       1. Devices Regulatory ensures that all relevant Economic Operators (Legal Manufacturer, Authorised Representative and Importer(s)) have registered with the Electronic System for Registration of Economic Operators in accordance with SOP-430597 EUDAMED Registration and Data Entry Maintenance.

NOTE: Following registration, the Competent Authority in the State where the Authorised Representative is located will verify the data entered into EUDAMED and obtain from the EUDAMED system a single registration number (SRN), which it will issue to the manufacturer, the authorized representative or the importer.

* + 1. Assignment of the Basic Unique Device Identification (BUDI)
       1. The Devices Regulatory Lead defines and assigns a Basic UDI-DI (BUDI) to the device in accordance with SOP-428058 EU UDI Management.
       2. Device Regulatory inputs the Basic UDI-DI into EUDAMED before placing the device on the market.
    2. General Safety and Performance Requirements
       1. Device Engineering completes the MDR General Safety and Performance Requirements Checklist using template APPX-441424.
    3. Conformity Assessment

NOTE: The scope of Notified Body intervention is determined by the Conformity Assessment Procedure [MDR annex(s)] applied. Notified Body intervention is not required for conformity assessment of class I, non-sterile, non-measuring devices.

* + - 1. Executive Director Level (or higher) personnel from Devices Regulatory, Operations Quality, Final Product Technology Quality selects a Notified Body with appropriate designation where intervention in the Conformity Assessment Procedure is required and appoints a Notified Body Representative as primary point of contact to coordinate communication between XXXXX and the Notified Body.

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NOTE: The Notified Body performs two main surveillance functions:

* + - * + Quality System assessment and monitoring
        + Product design examination
      1. Where appropriate, the Notified Body Representative coordinates review of the technical documentation by the Notified Body.
      2. Where appropriate, Quality coordinates assessment of the Quality System by the Notified Body.

NOTE: The authority responsible for Notified Bodies randomly samples and independently verifies the conclusions drawn by the Notified Body based on the information presented by the Legal Manufacturer. The reviews by the authority responsible for Notified Bodies are conducted both off-site and on-site and may or may not delay final certification.

* + - 1. The Legal Manufacturer’s Person Responsible for Regulatory Compliance signs the Declaration of Conformity on successful completing of the Conformity Assessment Procedure.

1. **Post Conformity Assessment**
   1. Post Market Surveillance
      1. Post Market surveillance is managed in accordance with SOP-430112 Post Market Surveillance for Medical Devices with CE Mark.
   2. Vigilance
      1. Vigilance is undertaken in accordance with SOP-427366 Medical Device Vigilance.
   3. Product and Quality System Lifecycle Management
      1. Consideration is given as to whether the Notified Body must be informed of any proposed change to a design which has been subject to Notified Body assessment. The Notified Body is informed of significant product changes as determined by GDE-403329 Multi-Site: Regulatory Assessor: Device Reporting Requirements.

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* + 1. Consideration is given as to whether or not the Notified Body must be informed of any proposed change to the quality system. The Notified Body is informed of substantial changes to the quality system as determined by GDE406809 Multi-Site: Regulatory Assessor: Reporting Requirements for Quality System Changes under Jurisdiction of a Notified Body.
    2. As a precaution XXXXX informs the Notified Body in advance of any plan to introduce a new medical device requiring Notified Body intervention.
    3. Devices Regulatory determines whether or not additional registration or notification requirements apply in any other Member State where the device is placed on the market.
    4. Conformity Assessment

NOTE: The scope of Notified Body intervention is determined by the Conformity Assessment Procedure [MDR annex(s)] applied. Notified Body intervention is not required for conformity assessment of class I, non-sterile, non-measuring devices.

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**APPENDIX A: GENERAL INFORMATION (PAGE 1 OF 2)**

**TERMS**

Identify all terms and definitions used within this document. Refer to the [XXXXX Glossary](http://edmquality.amgen.com/edmquality/drl/objectId/09014b2d8233e41f/versionLabel/CURRENT/format/pdf/chronicleId/09014b2d81663107) and the table below for definition of terms included in this document.

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| **Term** | **Definition** |
| *CE Mark* | Marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the MDR and other applicable Union legislation providing for its affixing. |
| *Placement on the market* | The first making available of a device, other than an investigational device, on the Union market. |
| *Legal Manufacturer* | 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. |
| *Authorised Representative* | Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks |
| *Basic-UDI-DI* | The Basic UDI-DI (BUDI) is an alphanumeric code used as the primary identifier of a device model.  It is the main access key for device-related information in the EUDAMED database and it is referenced in relevant documentation [e.g. certificates (including certificate of free sale), EU Declaration of Conformity, technical documentation and summary of safety and (clinical) performance)].  *It is intended to identify and connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics.* It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item. |
| *Notified Body* | A conformity assessment body designated in accordance with the MDR |
| *Conformity Assessment Procedure* | Process for demonstrating compliance with the applicable requirements |
| *Basic-UDI-DI* | The Basic UDI-DI (BUDI) is an alphanumeric code used as the primary identifier of a device model.  It is the main access key for device-related information in the EUDAMED database and it is referenced in relevant documentation [e.g. certificates (including certificate of free sale), EU Declaration of Conformity, technical documentation and summary of safety and (clinical) performance)].  *It is intended to identify and connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics.* It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item. |

**APPENDIX A: GENERAL INFORMATION (PAGE 2 OF 2)**

**TERMS (CONTINUED)**

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| **Term** | **Definition** |
| *EUDAMED* | EUDAMED is a web-access database operated by the European Commission which includes electronic systems for:   * registration of devices * UDI * registration of economic operators * notified bodies and certificates * clinical investigations * vigilance reporting and post-market surveillance market surveillance |

**ABBREVIATIONS**

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| **Abbreviation** | **Definition** |
| *EUDAMED* | European Database on Medical Devices |
| *MDR* | Medical Devices Regulation |
| *PRRC* | Person responsible for regulatory compliance |
| *SaMD* | Software as Medical Device |
| *UDI* | Unique Device Identifier |

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**APPENDIX B: REFERENCES AND RESOURCES (PAGE 1 OF 1)**

**REFERENCES**

The following documents are critical and necessary to perform the procedure.

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| **Document** | **Title** |
| Regulation (EU) 2017/745 | *European Medical Devices Regulation (EU MDR)* |
| [SOP-430926](https://amgencdocs.veevavault.com/ui/%23doc_info/2030852?state_type=steady_state__v) | *Global medical device/combination product determination process* |
| [SOP-428227](https://amgencdocs.veevavault.com/ui/%23doc_info/2022291?state_type=steady_state__v) | *Multisite - Procedure for Appointment of Key Roles in the QMS and Development of Job Descriptions* |
| [SOP-430597](https://amgencdocs.veevavault.com/ui/%23doc_info/2025393?state_type=steady_state__v) | *EUDAMED Registration and Data Entry Maintenance.* |
| [SOP-428058](https://amgencdocs.veevavault.com/ui/%23doc_info/2015763?state_type=steady_state__v) | *EU UDI Management* |
| [SOP-428902](https://amgencdocs.veevavault.com/ui/%23doc_info/2023692?state_type=steady_state__v) | *Preparation and Maintenance of MDR Technical Documentation* |
| [SOP-427826](https://amgencdocs.veevavault.com/ui/%23doc_info/2015531?state_type=steady_state__v) | *MDR Clinical Evaluation* |
| [SOP-430112](https://amgencdocs.veevavault.com/ui/%23doc_info/2024906?state_type=steady_state__v) | *Post Market Surveillance for Medical Devices with CE Mark* |
| [SOP-427366](https://amgencdocs.veevavault.com/ui/%23doc_info/2015071?state_type=steady_state__v) | *Medical Device Vigilance* |
| [GDE-403329](https://amgencdocs.veevavault.com/ui/%23doc_info/325077?state_type=steady_state__v) | *Multi-Site: Regulatory Assessor: Device Reporting Requirements* |

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