EU MDR REGULATORY STRATEGY

LunaAI

Abstract

This document outlines a comprehensive regulatory strategy for the LunaAI neurostimulation system, a Class III medical device designed to treat obstructive sleep apnea. It details the steps for achieving EU MDR compliance, including technical documentation preparation, risk management, post-market surveillance, and cybersecurity measures to ensure the device's safety and efficacy throughout its lifecycle.

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1. Purpose

a) Objective

The primary objective of this regulatory strategy document is to establish a comprehensive framework for achieving and maintaining compliance with the European Union Medical Device Regulation (EU MDR) 2017/745 for our **LunaAI** neurostimulation system.

This strategy aims to:

- Ensure LunaAI meets all applicable EU MDR requirements throughout its lifecycle.
- Facilitate smooth market access and continued presence in the European Economic Area (EEA)
- Maintain a high standard of safety and performance for patients and users.
- Streamline internal processes for efficient regulatory management.
- Provide clear guidance for cross-functional teams involved in regulatory activities.

b) Scope

This regulatory strategy encompasses the following key areas:

i) Geographical Markets:

- All 27 EU member states
- European Economic Area (EEA) countries: Norway, Iceland, and Liechtenstein
- Switzerland (through Mutual Recognition Agreement)

ii) Product Lifecycle Stages:

- Design and development
- Clinical investigations
- Manufacturing and quality control
- CE marking and initial market placement
- Post-market surveillance and vigilance
- Product updates and modifications

iii) Activities Covered:

- Technical documentation compilation and maintenance
- Risk management processes
- Clinical evaluation and post-market clinical follow-up (PMCF)
- Quality Management System (QMS) alignment with EU MDR
- Unique Device Identification (UDI) implementation

- Economic operator management (including authorized representatives and importers)
- Notified Body interactions and conformity assessment procedures
- EUDAMED registration and reporting
- Periodic Safety Update Report (PSUR) preparation
- Management of subcontractors and suppliers

c) Exemptions

The following areas are not applicable to this regulatory strategy:

- In vitro diagnostic medical devices (IVDs) regulated under IVDR 2017/746
- Custom-made devices as defined in Article 2(3) of EU MDR
- Investigational devices used solely within clinical investigations
- Non-medical devices listed in Annex XVI of EU MDR
- Combination products where the principal intended action is achieved by a medicinal product
- Strategies for obtaining market authorization outside the EEA (e.g., FDA approval for the United States market)
- Regulatory processes specific to EU member state-level requirements beyond the scope of EU MDR

This regulatory strategy focuses exclusively on the LunaAI neurostimulation system and its accessories. It does not cover any other products in NightBreath Technologies' portfolio or potential future devices that may be developed.

2. Device and Manufacturer Information

a) Device Description

LunaAI is an innovative implantable neurostimulation system designed to treat obstructive sleep apnea (OSA). The system comprises three main components:

- **NightPulse Generator:** A small, programmable device implanted in the upper chest.
- **BreathSense Lead:** A sensor placed between the ribs to detect breathing patterns.
- **TongueTone Lead:** A stimulation lead connected to the hypoglossal nerve.

The NightPulse Generator contains advanced proprietary software called SleepRhythm AI, which continuously monitors the patient's breathing patterns during sleep. When it detects an

impending airway obstruction, it delivers precisely calibrated electrical pulses through the TongueTone Lead to the hypoglossal nerve. This stimulation causes the tongue to move forward, opening the airway and allowing for unobstructed breathing.

Device Purpose and Mechanism of Action

LunaAI is designed to address obstructive sleep apnea by detecting breathing irregularities and applying electrical stimulation to the hypoglossal nerve, which activates the tongue muscles and prevents airway collapse. The system operates in three key phases:

- **Monitoring:** The breathing sensor continuously monitors respiratory effort.
- **Detection:** Proprietary software algorithms analyze respiratory data to identify apnea events.
- **Stimulation:** Based on detection results, the pulse generator delivers controlled electrical pulses to the hypoglossal nerve, ensuring airway patency.

b) Intended Use and Indications

i) Intended Use

LunaAI is intended for use in adult patients with moderate to severe OSA who are unable to use or benefit consistently from continuous positive airway pressure (CPAP) therapy. The device is designed to be used during sleep to maintain airway patency.

ii) Indications for Use

LunaAI is indicated for patients aged 22 and older with:

- Moderate to severe OSA (Apnea-Hypopnea Index [AHI] between 15 and 100 events per hour)
- Body Mass Index (BMI) ≤ 40 kg/m^2
- Less than 25% central sleep apnea events
- Inability to use or tolerate positive airway pressure treatments
- Absence of complete concentric collapse at the soft palate level

iii) Intended Purpose

The primary clinical benefits of LunaAI include:

- Significant reduction in AHI and oxygen desaturation events
- Improved sleep quality and daytime functioning
- Enhanced quality of life for OSA patients
- Preservation of natural airway anatomy

Target users include sleep medicine physicians, otolaryngologists, and adult patients with OSA who meet the eligibility criteria and have failed or cannot tolerate CPAP therapy.

c) Manufacturer Details

i) Legal Manufacturer

Manufacturer	NightBreath Technologies, Inc.
Address	1234 Innovation Drive Sleepville, CA 90210, USA
Phone	+1 (800) 555-1234
Email	info@nightbreath.com

ii) Regulatory Role

EU Authorized Representative:	EuroSleep Medical Devices GmbH
Address	Schlafstraße 42, 10115 Berlin, Germany
Phone	+49 30 1234567
Person Responsible for Regulatory Compliance (PRRC)	Dr. Maria Roggers
Email	m.roggers@nightbreath.com

iii) Manufacturing Sites

Primary Manufacturing Facility	NightBreath Production Center
Address	5678 Assembly Lane, Sleepville, CA 90210, USA
R&D Center	NightBreath Innovation Hub 910 Research
Address	Boulevard, TechCity, MA 02142, USA
European Operations:	NightBreath EU Logistics Center
Address	Idustriestraße 15 60314 Frankfurt, Germany

Software Development Center	NightBreath Code Labs
Address	789 Algorithm Avenue, Silicon Valley, CA 94041, USA

3. Regulatory Classification

a) Device Classification

Risk Class:

Based on the intended use and characteristics of LunaAI, the device is classified as a **Class III medical device** under the EU Medical Device Regulation (MDR) 2017/745. The classification is determined by the application of the following rules from Annex VIII of the MDR:

- **Rule 8**: Implantable and long-term surgically invasive devices are classified as Class IIb unless intended to administer medicinal products, in which case they are classified as Class III. LunaAI qualifies as an implantable device.
- **Rule 22**: Active therapeutic devices with an implantable component intended to treat or alleviate a condition through stimulation of neural tissues are classified as Class III.

b) Justification

LunaAI is an implantable neurostimulation system designed to treat obstructive sleep apnea (OSA) by stimulating the hypoglossal nerve. The following rationale supports its classification:

i) Implantable Nature:

The device includes a pulse generator implanted in the chest and leads connected to the hypoglossal nerve and breathing sensors. According to Rule 8, all implantable devices are subject to at least Class IIb classification. However, since LunaAI directly interacts with neural tissues, Rule 22 elevates it to Class III.

ii) Active Therapeutic Function:

LunaAI employs advanced proprietary software in its pulse generator to deliver therapeutic neurostimulation in response to detected breathing irregularities. The stimulation directly affects the functioning of the upper airway by activating the hypoglossal nerve.

iii) Potential Overlaps Addressed:

- While LunaAI includes software that qualifies as a **Software as a Medical Device (SaMD)**, it is integrated within the implantable device and thus classified under Rule 22, rather than Rule 11 (standalone SaMD).
- The device's primary mode of action is neurostimulation rather than diagnostic; therefore, it is not classified under Rule 10 or other diagnostic device rules.

Rule	Description	Relevance	Outcome
Rule 8	Implantable, long-term surgically invasive device	Relevant	Proceeds to Rule 22
Rule 22	Active implantable device with a therapeutic effect on neural tissue	Relevant	Class III
Rule 11	Software as a Medical Device (SaMD)	Not Applicable	integrated in device
Final Decision	Class III due to implantable nature and active therapeutic effect		

4. Market Entry Plan

a) Marketed Device Jurisdictions

i) Target Countries:

All the 27 states in the European Union (EU)

ii) Regulatory Requirements:

EU: Compliance with **MDR 2017/745**; obtain CE marking through conformity assessment.

b) Regulatory Pathway

i) Conformity Assessment Route (EU):

For Class III devices, conformity assessment via Annex VIII of the MDR. Annex VII of the EU MDR (2017/745) sets the requirements for Notified Bodies conducting conformity assessments. It ensures their independence, competence, and impartiality while mandating robust quality management systems, qualified personnel, and liability coverage. Notified Bodies must evaluate technical documentation, audit QMS, and perform

unannounced audits. Competent authorities oversee their compliance to maintain high safety and performance standards for medical devices in the EU.

ii) Notified Body Engagement:

In the European Union (EU), Class III medical devices, which are considered high-risk, require a conformity assessment conducted by a Notified Body before they can be marketed. Notified Bodies are organizations designated by EU member states to assess the conformity of medical devices with applicable regulations. ("What is CE marking and certification? - Matrix Requirements") Each country has their own notified body such as

- BSI **Group (British Standards Institution)** – UK and Netherlands
  Known for certifications in various industries, including medical devices.
- TÜV **SÜD** – Germany
  A prominent Notified Body for medical devices and in vitro diagnostics.
- SGS **Belgium NV** – Belgium
  Offers certification and testing services for medical devices.
- DEKRA **Certification GmbH** – Germany and Netherlands
  Recognized for its expertise in medical device assessments.

Role of Notified Bodies for Class III Devices:

For Class III medical devices, Notified Bodies perform a comprehensive evaluation that includes:

- Reviewing the manufacturer's quality management system.
- Assessing the technical documentation of the device.
- Evaluating clinical data to ensure the device's safety and performance.

This thorough assessment ensures that high-risk medical devices meet the stringent requirements set forth by the EU Medical Device Regulation (MDR) (Regulation (EU) 2017/745).

Finding a Notified Body:

Manufacturers seeking a Notified Body for their Class III devices can refer to the European Commission's NANDO (New Approach Notified and Designated Organization's) database. This database provides a list of Notified Bodies designated to carry out conformity assessments under the MDR.

c) Regulatory Timeline

Key Milestones with Estimated Dates:

- **Preliminary design dossier preparation and testing**

  Estimated Date: January 2025 – March 2025.

  This phase includes finalizing device design, performing initial safety and performance tests, and preparing the technical dossier.
- **Submission of the technical documentation to the Notified Body or equivalent authority**

  Estimated Date: June 2025.

  By this point, the device's technical documentation, including clinical evaluation, risk analysis, and QMS, should be ready for submission.
- **Review and scrutiny phase, including potential follow-ups**

  Estimated Date: July 2025 – December 2025.

  During this phase, the Notified Body reviews the submission and may request clarifications or additional data.
- **Expected CE marking approval and simultaneous market entry planning for the EU**

  Estimated Date: December 2025 – January 2026.

  Approval is expected after successfully addressing the Notified Body's queries. Simultaneous planning for market entry, including distribution coordination and labeling, should be in progress.

Final Estimated Dates for CE Marking and Market Entry:

- **Submission:** June 2025
- **Review Completion:** December 2025
- **Market Launch:** Q1 2026 (January–March 2026)

d) Scrutiny Procedure (EU)

Class III devices may require **additional scrutiny** under **Article 54 of MDR**:

- **Notified Body Review**: Review of clinical evidence and technical documentation.
- **Competent Authority Involvement**: The Notified Body may involve a Competent Authority to confirm compliance.

- **Independent Review**: Additional verification by independent panels if deemed necessary.

e) Expert Panel Consultation

i) Applicability:

- For **novel Class III devices** or those with new intended uses, consultation with the **EU Expert Panel** may be required.

ii) Plan for Consultation:

- Submit clinical evaluation data and intended use details to the Expert Panel during the pre-submission phase.
- Allocate time for additional review and integration of Expert Panel feedback into the submission package.

Adjust the timeline to accommodate potential Expert Panel queries or requests for additional testing.

5. Legal and Regulatory Requirements

a) Applicable Standards and Specifications

i) ISO 13485:2016 - Quality Management Systems (QMS)

ISO 13485 specifies the requirements for a QMS in medical device manufacturing to ensure consistent design, development, production, and post-market activities. For LunaAI, adherence demonstrates that NightBreath Technologies has a robust QMS supporting regulatory compliance and patient safety.

Application:

- Document control must ensure all records, such as SOPs for design controls and software updates, are maintained, version-controlled, and auditable.
- Supplier control processes are essential for the breathing sensor and stimulation lead manufacturers to ensure conformity with specified requirements.
- Internal audits must be conducted bi-annually to verify compliance with ISO 13485 and MDR.
- Night Breath Technologies achieves ISO 13485 certification with the QMS scope explicitly covering implantable neurostimulation systems.

- Quality Objectives include reducing manufacturing defects from 5% to 3% within 12 months.

ii) IEC 62304:2006+A1:2015 - Software Lifecycle Processes

IEC 62304 provides a framework for software lifecycle activities, including risk management, software maintenance, and problem resolution. Given the criticality of LunaAI's software, compliance ensures software reliability and safety.

Application:

- Development must follow a documented software development plan. Key phases include:
- Software Requirements Analysis: Detailing functions like apnea event detection and stimulation timing.
- Software Architecture Design: Ensuring modularity for easy updates.
- Software Verification & Validation (V&V): Conduct testing to ensure each software module functions as intended.
- Maintenance processes should address software bug fixes and updates based on postmarket feedback.
- A failure in breathing pattern detection is identified during testing (accuracy = 95%, target = 99%). Developers enhance the algorithm to achieve the target.

iii) ISO 14971:2019 - Risk Management

ISO 14971 establishes a structured approach to risk management, focusing on hazard identification, risk analysis, evaluation, and mitigation throughout the product lifecycle.

Application:

Key risks for LunaAI include:

- Electrical overstimulation: Risk of patient discomfort or harm.
- Software malfunction: Failure to detect apnea, leading to untreated events.
- Mitigation measures include implementing redundant breathing sensors and thorough software testing.

A risk assessment identifies that stimulation overshoot has an initial risk score of 15 (high). Mitigating this with a sensor cross-check mechanism reduces the residual risk to 4 (low).

iv) IEC 62366-1:2015 - Usability Engineering

IEC 62366-1 emphasizes usability engineering to minimize errors during use. This is critical for ensuring that healthcare professionals can safely and effectively implant and monitor LunaAI.

Application:

- Conduct usability tests with surgeons to ensure the implantation process is straightforward and minimizes patient risk.
- Develop user manuals and training materials tailored to surgeons and healthcare providers.
- Simulated implantation scenarios reveal that 95% of surgeons can correctly implant LunaAI on the first attempt. Recommendations include clearer labeling for lead connections.

b) Regulations

i) EU MDR (Regulation (EU) 2017/745)

The EU MDR sets stringent requirements for Class III devices, including clinical evaluation, postmarket surveillance, and conformity assessment.

Application:

- A Notified Body will assess LunaAI's compliance through a detailed review of its technical documentation and QMS.
- MDR labeling requirements necessitate clear instructions, contraindications, and the inclusion of a UDI on device packaging.
- Establish a post-market surveillance (PMS) system to collect data on device performance aftermarket launch.
- LunaAI's clinical performance is monitored through a PMS plan requiring bi-annual surveys from 100 healthcare facilities.

ii) GDPR (General Data Protection Regulation)

Since LunaAI processes patient breathing data, GDPR compliance is critical for ensuring data security and patient privacy.

Application:

- Implement robust data encryption during wireless transmission from the breathing sensor to the pulse generator.
- Draft clear patient consent forms detailing data collection and storage procedures.

- A patient consent form includes a clause: “Your breathing data is securely stored and used only to improve LunaAI’s performance. You may withdraw consent anytime by contacting info@nightbreath.com.”

c) Common Specifications (CS)

EU Common Specifications set additional mandatory requirements for specific devices. For LunaAI, the CS for implantable neurostimulation devices may apply.

Application:

- If applicable, CS compliance involves performance benchmarks for electrical stimulation safety and biocompatibility.
- Biocompatibility testing under ISO 10993 ensures all materials are safe for long-term implantation.

6. Technical Documentation Preparation

a) General Safety and Performance Requirements (GSPR)

Address all applicable GSPRs listed in Annex I of the MDR. Include evidence demonstrating **compliance.**

Application:

- Document conformance to biocompatibility (ISO 10993), electrical safety (IEC 60601-1), and software performance (IEC 62304).
- GSPR 10.4: Breathing sensor accuracy validated under simulated patient conditions. The report shows 98% detection accuracy.

b) Clinical Evaluation Report (CER)

The CER demonstrates that LunaAI is safe and effective based on clinical and pre-clinical data.

Application:

- Include results from a clinical trial with 100 patients showing a significant reduction in apnea episodes.
- Data shows an apnea reduction rate of 85% with no serious adverse events in 95% of patients.

c) Risk Management File

Integrates risk analysis, evaluation, and mitigation documentation.

Application:

- Risk control measures include dual-sensor mechanisms and a failsafe shutdown protocol for software malfunctions.
- The Risk Mitigation Table shows a reduction in electrical stimulation errors by 80% after implementing redundant signal verification.

d) Software Lifecycle Documentation

Includes all documents related to software development and validation.

Application:

- Provide a Software Design Specification (SDS) detailing algorithms and functionality.
- Include test reports showing >99% reliability under stress conditions.
- Test report confirms successful detection of apnea events in 99.5% of simulated cases.

e) Usability and Cybersecurity Testing Reports

To ensure LunaAI is safe, user-friendly, and secure.

Application:

- Conduct usability testing with 20 surgeons and implement recommendations based on feedback.
- Perform penetration testing to identify and mitigate cybersecurity risks.
- Usability testing reveals that labeling improvements increase successful first-time implantation rates by 15%.

f) Summary of Safety and Clinical Performance (SSCP)

To provide a publicly accessible summary of clinical data and safety information for LunaAI, ensuring transparency and compliance with EU MDR requirements.

Application:

- Create a comprehensive SSCP document for LunaAI, as it is a Class III implantable device.
- Include separate sections for healthcare professionals and patients, using appropriate language for each audience.
- Summarize LunaAI's safety, performance, and clinical benefits in treating obstructive sleep apnea.
- Update the SSCP at least annually, incorporating new clinical data and post-market surveillance information.

- Submit the SSCP for validation by the Notified Body before uploading to EUDAMED for public access.

g) Periodic Safety Update Report (PSUR)

To systematically assess and document LunaAI's risk-benefit ratio throughout its lifecycle, based on post-market surveillance data.

Application:

- Prepare and update the PSUR for LunaAI annually, as required for Class III devices.
- Summarize results and conclusions from post-market surveillance activities outlined in the Post-Market Surveillance Plan (PMSP).
- Submit the PSUR to the Notified Body via EUDAMED for review and evaluation.
- Incorporate PSUR findings into the technical documentation for LunaAI.

7. Product Realization

The following subsections address the manufacturing activities, packaging, labeling, batch verification, UDI implementation, and distribution strategy for the LunaAI system.

a) Manufacturing Activities

Key Processes	Details
Primary Manufacturing	The NightBreath Production Center in Sleepville, CA, oversees device assembly, software integration, and quality assurance testing.
Outsourced Activities	Certain components, such as the breathing sensor and stimulation lead, are manufactured by ISO 13485-certified suppliers in Germany and Japan.
Sterilization	Outsourced to an ISO 11137-certified sterilization provider in Frankfurt, Germany.
Final Testing	Electrical and software functionality testing was conducted at the Primary Manufacturing Facility.

b) Packaging and Labeling

i) The packaging and labeling processes comply with **Annex I, Chapter III of EU MDR** to ensure traceability, safety, and proper information dissemination.

Key Labeling Elements	Example Information

Manufacturer's Name and Address	NightBreath Technologies, Inc., 1234 Innovation Drive, Sleepville, CA 90210, USA
Product Name	LunaAI Neurostimulation System
UDI Carrier	Example: Barcode and human-readable Basic UDI-DI: 123456789-LUNA1
Warnings and Precautions	"For single use only. Sterile unless packaging is damaged. Consult the User Manual before use."
EU Authorized Representative Info	EuroSleep Medical Devices GmbH, Schlafstraße 42, 10115 Berlin, Germany
Compliance Mark	CE Mark with Notified Body Identification Number (e.g., CE 0123)

Label Example:

LunaAI Neurostimulation System

Class III Medical Device

Legal Manufacturer: NightBreath Technologies, Inc., USA

EU Authorized Representative: EuroSleep Medical Devices GmbH, Germany

UDI-DI: 123456789-LUNA1

Warnings: "Do not reuse. Sterile unless damaged. CE 0123."

ii) Instructions for Use (IFU)

General Requirements

- The IFU is mandatory for lunaAI as it is a Class III medical device.
- The IFU must be provided in human-readable format and may also be supplemented with an electronic version (eIFU).

Content of IFU

The IFU for lunaAI should include:

- **Device Identification**

  Product name: lunaAI

  Manufacturer's details

  UDI (Unique Device Identifier)

- **Intended Purpose**

  A detailed description of the intended purpose of lunaAI

  Expected clinical benefits

- **Performance Characteristics**

Specific performance characteristics of lunaAI

- **Safety Information**

  Residual risks, contraindications, and potential side effects

  Warnings and precautions

- **Usage Instructions**

  Proper installation and use of lunaAI

  Any specific requirements for facilities or user qualifications

- **Software-Specific Information**

  "Minimum requirements for hardware, IT network characteristics, and IT security measures" ("Medical Device IFU & eIFU ")

- **Maintenance and Updates**

  Information on software updates and potential cybersecurity measures

Additional Considerations

- **Language Requirements:** Ensure the IFU is available in all official languages of the EU member states where lunaAI will be marketed.
- **eIFU Provision**: Include the web address (URL) for accessing the eIFU on the device labeling.
- **Version Control**: Include the date of issue or latest revision of the IFU.
- **Alignment with Other Documents**: Ensure consistency between the IFU content and other regulatory documents such as the Clinical Evaluation Report (CER) and risk management files.

c) Batch Verification

Batch verification is a critical quality assurance process for **Class III implantable medical devices** like the LunaAI Neurostimulation System. It ensures compliance with EU MDR safety, performance, and quality requirements before the product is released to the EU market. The process involves collaboration with the designated Notified Body (e.g., TÜV SÜD) and includes the following steps:

i) Sampling Inspections of Finished Devices

- The Notified Body performs sampling inspections of the finished devices to ensure alignment with the **Technical Documentation** submitted during the conformity assessment.
- Key inspection criteria include:

Verification of physical and mechanical integrity of the device.

Functional testing of the pulse generator and its software.

Assessment of compliance with sterilization and biocompatibility requirements.

ii) Review of Sterilization Validation Data and Batch Records

- **Sterilization Validation Data**:

  Review sterilization protocols to confirm compliance with **ISO 11137** standards.

  Evaluate parameters such as sterilant concentration, exposure time, and temperature.

- **Batch Records**:

  Detailed examination of manufacturing and quality control records for each batch.

  Ensure traceability of raw materials, components, and finished goods.

  Confirm that all deviations, if any, are resolved, and corrective actions are implemented.

iii) Issuance of a Batch Certificate

- Upon successful completion of the inspections and data reviews, the Notified Body issues a **Batch Certificate**, authorizing the release of that batch for distribution in the EU.
- The certificate is linked to the specific batch and included in the regulatory documentation maintained by NightBreath Technologies.

d) UDI Implementation

The Unique Device Identifier (UDI) is a mandatory labeling requirement under EU MDR to ensure traceability and transparency throughout the device's lifecycle.

i) Basic UDI-DI and Individual Device UDI

- **Basic UDI-DI**: Identifies the LunaAI device model. Example: 123456789-LUNA1.
- **Individual Device UDI**: Unique to each manufactured unit. Example: 123456789-LUNA1-SERIAL01.

ii) Steps for UDI Compliance

- **Integration into Packaging and Labeling**:

The UDI barcode and human-readable format are incorporated on both the primary and secondary packaging.

Ensure labels comply with **Annex I, Chapter III** of EU MDR, including additional information like lot numbers, expiry dates, and storage conditions.

iii) UDI Database Maintenance:

- Develop and maintain a centralized **UDI Database** to record and track devices throughout their lifecycle.
- Link each UDI to batch records, manufacturing dates, and distribution channels.

iv) EUDAMED Registration:

- Register the **Basic UDI-DI** and device-related information in the EUDAMED database.
- Ensure alignment with the EU Authorized Representative (Euro Sleep Medical Devices GmbH).
- Periodically update EUDAMED entries to reflect post-market changes or recalls.

e) Distribution and Supply Chain

The LunaAI distribution strategy prioritizes compliance with EU MDR requirements and ensures device availability while maintaining safety and traceability standards.

i) Logistics Operations

- The **NightBreath EU Logistics Center** in Frankfurt, Germany, manages device warehousing, distribution, and shipment tracking within the European Union.
- The center follows Good Distribution Practices (GDP) to maintain device integrity during storage and transit.

ii) Distributor Roles and Responsibilities

- **Traceability via UDI System**:

  Distributors ensure that the UDI is logged and traceable for all devices in their supply chain.

  Each distributor must maintain a record of UDI-related data, including recipient information and batch details.

- **Inventory Management**:

  Maintain inventory under controlled conditions as specified by the device's labeling (e.g., temperature, humidity).

  Conduct periodic audits to ensure compliance with EU MDR.

- **Post-Market Surveillance (PMS)**:

Collect and report device performance data, complaints, or adverse events to the manufacturer.

Facilitate returns or recalls in collaboration with the NightBreath EU Logistics Center.

- **Key Compliance Documentation**

  Signed agreements with distributors, defining their roles in traceability, reporting, and PMS activities.

  Detailed standard operating procedures (SOPs) outlining organization and distributor responsibilities under EU MDR.

8. Risk Management

The risk management process aligns with ISO 14971:2019 and emphasizes lifecycle risk control, benefit-risk analysis, and cybersecurity measures.

a) Plan and Process

The risk management process ensures the identification, evaluation, control, and monitoring of risks throughout the device lifecycle.

Risk Management Step	Description
Risk Identification	Identify hazards related to device design, software, manufacturing, and use.
Risk Evaluation	Assess risks based on the probability of occurrence and severity of harm.
Risk Control	Implement mitigation measures such as alarms, fail-safe mechanisms, and labeling precautions.
Residual Risk Review	Evaluate and document residual risks to ensure the overall benefit outweighs the risks.

b) Design and Development Risks

Key risks identified during the design and development phase, along with mitigation strategies, are as follows:

i) Software-Related Risks

- **Risk**: Vulnerabilities in the pulse generator software, including potential cybersecurity breaches.
- **Mitigation**:

  Implement robust encryption protocols to safeguard data.

  Conduct regular software vulnerability assessments and provide firmware updates.

Integrate fail-safe features to maintain functionality during software issues.

ii) Usability and Interoperability Risks

- **Risk:** Difficulty for patients to use the device effectively or interference with other medical devices.
- **Mitigation:**

  Develop user-friendly interfaces and provide comprehensive user training materials.

  Conduct interoperability testing to ensure compatibility with other medical equipment.

  Utilize simulated use environments during clinical trials to identify and address usability issues.

c) Benefit-Risk Analysis

For a **Class III device** like LunaAI, benefit-risk analysis is critical to justify its use and obtain regulatory approval.

- **Benefits**:

  Significant reduction in obstructive sleep apnea (OSA) episodes.

  Improved quality of life, including better sleep patterns and reduced daytime fatigue.

  Non-invasive airway management compared to continuous positive airway pressure (CPAP) devices.

- **Risks**:

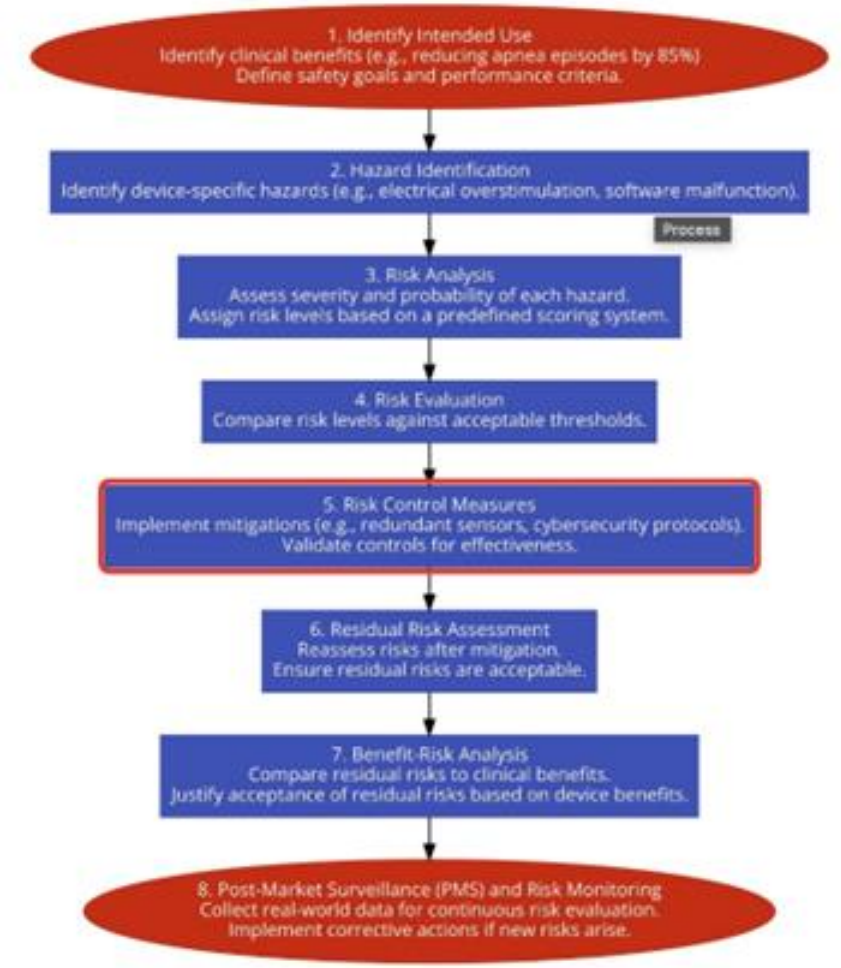
  Surgical risks such as infection or implant rejection.

  Device malfunctions, including failure of the pulse generator or leads.

  Residual airway obstruction despite device activation.

The analysis demonstrates that the substantial clinical benefits of LunaAI outweigh the potential risks, particularly for patients unresponsive to existing OSA treatments.

Flowchart for Benefit-Risk Analysis and Risk Management



d) Residual Risks

Residual risks are minimized through design and mitigation strategies but are clearly communicated to patients and healthcare providers via the **Patient Information Leaflet (PIL)** and labeling.

Residual Risk	**Communication Method**
Allergic reaction to the implant	Explicit warning included in the PIL and device labeling.
Device failure	Emergency contact information and a troubleshooting guide provided in the PIL.
Cybersecurity breach	Inclusion of data protection measures in user manuals and consent forms.

e) Cybersecurity

Cybersecurity is a key focus area, addressing risks such as unauthorized access, data breaches, and compromised functionality.

- **Encryption**

  Implement end-to-end encryptions for all patient data stored or transmitted by the pulse generator.

- **Authentication**

  Introduce multi-factor authentication (MFA) for healthcare professionals accessing the software.

  Require unique identifiers for user sessions to track access history.

- **Regular Updates**

  Schedule mandatory firmware updates to patch vulnerabilities and maintain system integrity.

  Notify users of critical updates via secure communication channels.

- **Incident Response Plan**

  Establish a cybersecurity response team to address breaches or failures promptly.

  Maintain logs of security incidents and share findings in post-market surveillance reports.

9. Post-Market Surveillance

a) PMS Plan

i) Purpose

The purpose of this Post-Market Surveillance Plan (PMSP) is to establish a structured approach for continuously monitoring the performance and safety of the LunaAI System. The plan ensures compliance with EU MDR 2017/745 and supports the identification of risks, adverse events, and opportunities for product improvement, contributing to enhanced patient safety and device efficacy.

ii) Scope

This PMSP applies to all models and configurations of the LunaAI Neurostimulation System, including its pulse generator, breathing sensor lead, and stimulation lead, across all regions

where the device is marketed. It covers data collection, analysis, and reporting activities aimed at ensuring ongoing compliance and product performance.

iii) Device Description and Background

LunaAI is an innovative, implantable neurostimulation system designed to treat moderate to severe obstructive sleep apnea (OSA) by stimulating the hypoglossal nerve to maintain an open airway during sleep. The system comprises:

- **Pulse Generator:** Implanted in the upper chest, monitors breathing patterns, and delivers stimulation.
- **Breathing Sensor Lead:** Placed between the ribs, detects respiratory signals.
- **Stimulation Lead:** Attached to the hypoglossal nerve, provides mild electrical stimulation to reposition the tongue.

LunaAI is intended for adult patients who have not tolerated or failed positive airway pressure (PAP) therapy, offering a less invasive alternative to traditional surgical methods.

iv) Potential Risks

Key risks associated with LunaAI include:

- **Device Malfunctions:** Hardware or software failures that may impair therapy effectiveness.
- **Adverse Events:** Risk of infection, nerve damage, or discomfort at the implant site.
- **Stimulation Issues:** Inappropriate stimulation levels leading to tongue movement restrictions or discomfort.
- **Battery and Connectivity Issues:** Battery depletion or communication issues between components.

v) Data Collection

Data will be collected from the following sources to ensure comprehensive monitoring of device performance and safety:

- **Clinical Feedback and Complaints:** Reports from healthcare professionals and patients regarding device performance and adverse events.
- **Feedback Surveys:** Structured surveys distributed to customers and healthcare providers to gather insights on device usage, satisfaction, and any observed issues.
- **Distributor Feedback:** Input from distributors regarding device handling, storage conditions, and customer feedback.

vi) **Post-Market Clinical Follow-Up (PMCF):** Ongoing clinical studies to assess long-term safety and effectiveness outcomes.

- **Vigilance Reporting:** Incident and adverse event reporting through the EUDAMED system.
- **Scientific Literature:** Regular reviews of published research relevant to OSA treatments and neurostimulation devices.
- **Internal Quality Data:** Non-conformance reports, audit findings, and CAPAs from the quality management system (QMS).

vii) **Data Assessment**

- **Trend Analysis:** Data will be analysed using statistical tools to identify patterns and trends in adverse events, complaints, and feedback.
- **Risk Evaluation:** Findings will be used to update the risk management file, ensuring the device's risk-benefit profile remains favourable.
- **Corrective and Preventive Actions (CAPA):** Root cause analysis will inform corrective and preventive measures to address identified issues.
- **Regulatory Reporting:** Results of the data assessment will be documented in Periodic Safety Update Reports (PSURs) and submitted to regulatory authorities as required.
- This PMSP ensures that LunaAI's safety and performance are continuously monitored and maintained, supporting compliance and patient well-being.

b) Periodic Safety Update Report (PSUR) Strategy for LunaAI

This strategy integrates EU MDR requirements, ensuring compliance with Article 86 for PSUR preparation, submission, and ongoing updates throughout the device's lifecycle.

i) Purpose

The PSUR summarizes post-market surveillance (PMS) data collected as per Article 84, aligning with the requirements for Class III devices.

ii) Scope

- Applies to LunaAI, a Class III implantable neurostimulation system for treating obstructive sleep apnea (OSA).
- Covers annual updates of the PSUR for submission to the Notified Body via the EUDAMED system as mandated by Article 92.

iii) PSUR Development and Content

The PSUR will include the following:

- **Conclusions of the Benefit-Risk Determination**

  Comprehensive analysis of safety and performance data gathered post-market.

  Documentation demonstrating that the benefit-risk balance remains favourable based on real-world data.

- **Main Findings of the PMCF**

  Key insights from PMCF studies, including:

  Reduction in Apnea-Hypopnea Index (AHI).

  Performance validation and safety data for various patient demographics.

- **Sales and Usage Data**
- **Volume of Sales:** Detailed reporting on units sold per region.
- **Population Size and Characteristics:** Estimation of device users, including demographic data such as age, gender, and comorbidities.
- **Usage Frequency:** Evaluation of adherence to prescribed use patterns (e.g., nightly usage during sleep).

iv) Submission Requirements

- **Annual Updates for Class III Devices**

  The PSUR will be updated annually and submitted electronically to the Notified Body as per Article 92.

  The Notified Body will evaluate the report and provide feedback or recommendations for any required actions.

- **Serious Incident Reporting**

  Serious incidents or field safety corrective actions (FSCAs) will be reported within 15 days via EUDAMED, as required under MDR vigilance guidelines.

- **Availability to Competent Authorities**

  PSURs, along with the Notified Body's evaluation, will be accessible to Competent Authorities through the EUDAMED system.

v) Integration with Technical Documentation

- The PSUR will form part of the technical documentation under Annexes II and III.
- Any updates to safety, performance data, or CAPAs will be integrated into the risk management file and PMS documentation.

vi) Corrective and Preventive Actions (CAPAs)

- **CAPA Implementation:** Address issues identified in PMS or PMCF data, including root cause analysis and preventive measures.
- **Monitoring Effectiveness:** Verify the impact of CAPAs through trend analysis and follow-up reports.

vii) Responsibilities

- **Regulatory Affairs Team:** Preparation and submission of the PSUR and coordination with the Notified Body.
- **Post-Market Surveillance Team:** Collection and analysis of data from PMS and PMCF activities.
- **Quality Assurance Team:** Ensuring CAPA implementation and effectiveness monitoring.

viii) Continuous Monitoring

- **Data Gathering:** Ensure robust collection of real-world data through surveillance tools, user feedback, and clinical evaluations.
- **Risk Management Updates:** Update the risk management file based on findings from the PSUR and PMCF activities.
- **Lifecycle Management:** Ensure ongoing compliance and readiness for inspections or audits.

ix) Conclusion

This strategy ensures that the PSUR process for LunaAI adheres to EU MDR requirements, facilitates timely updates and submissions, and supports the continuous monitoring of safety and performance for regulatory compliance.

c) Post-Market Clinical Follow-Up (PMCF) Plan for LunaAI Neurostimulation System

The **Post-Market Clinical Follow-Up (PMCF)** plan is a key component of the regulatory strategy for the LunaAI Neurostimulation System, aimed at ensuring the device's continued safety and effectiveness after it is placed on the market. PMCF activities involve collecting clinical data to evaluate long-term device performance, identify any emerging risks, and contribute to the overall risk management process.

i) Purpose of PMCF

The purpose of the PMCF plan is to:

- Continuously assess the clinical performance and safety of LunaAI in real-world use.

- Provide additional evidence to support the ongoing risk-benefit evaluation of the device.
- Ensure compliance with the EU MDR requirements for post-market surveillance and clinical evaluation.
- Collect real-world data to support regulatory submissions, product improvements, and potential label expansions.

ii) Scope of PMCF

The PMCF plan applies to all patients using the LunaAI Neurostimulation System, including those who have implanted the pulse generator and connected leads. It includes both the primary clinical monitoring of device efficacy and safety, as well as studies that gather feedback on patient quality of life and long-term outcomes related to obstructive sleep apnea (OSA).

iii) Device Description and Background

LunaAI is an implantable neurostimulation system for treating moderate to severe obstructive sleep apnea (OSA) in adult patients who are unable to tolerate or have failed positive airway pressure (PAP) therapy. The system includes:

- **Pulse Generator:** Monitors and stimulates the hypoglossal nerve to maintain airway patency during sleep.
- **Breathing Sensor Lead:** Detects respiratory patterns and provides data to the pulse generator.
- **Stimulation Lead:** Delivers electrical stimulation to the hypoglossal nerve to move the tongue forward and prevent airway collapse.

iv) PMCF Objectives

The primary objectives of the PMCF are to:

- Monitor long-term clinical safety and performance of LunaAI in patients with obstructive sleep apnea (OSA).
- Collect data on any complications, device malfunctions, and adverse events.
- Evaluate the effectiveness of the device in preventing airway obstruction and improving sleep quality over extended periods.
- Gather data on patient quality of life (QoL) using validated instruments such as the **Epworth Sleepiness Scale (ESS)** and the **Functional Outcomes of Sleep Questionnaire (FOSQ)**.

- Identify potential improvements in device design, settings, or therapy delivery based on clinical observations.

v) PMCF Methodology

The PMCF activities will include the following methods:

- **Clinical Studies:**

  Longitudinal Follow-Up Studies: Ongoing studies to monitor safety and effectiveness over time (e.g., 12-month, 24-month, and 36-month follow-ups).

  Randomized Controlled Trials (RCTs): Evaluate therapy effectiveness compared to standard treatments.

- **Patient and Physician Surveys:**

  Structured surveys to gather subjective feedback on patient satisfaction, device usability, and quality of life improvements.

  Surveys targeting healthcare providers to assess clinical outcomes, therapy adjustments, and challenges in device management.

- **Post-Implantation Monitoring:**

  Regular in-laboratory sleep studies (Polysomnography or PSG) to assess improvements in apnea-hypopnea index (AHI), oxygen desaturation index (ODI), and overall sleep quality.

  Continuous monitoring through follow-up visits to assess any complications or adverse events.

- **Patient Registries:**

  Data from patient registries to monitor safety and track long-term outcomes in larger patient populations.

vi) PMCF Data Collection

Data will be collected from multiple sources, including:

- **Clinical Feedback:** Data from ongoing clinical trials, observational studies, and patient registries.
- **Device-Related Feedback:** Reports of device performance, adverse events, and any reprogramming or surgical interventions.
- **Quality of Life Assessments:** Using instruments such as **FOSQ** and **ESS** to measure improvements in daytime sleepiness and overall functioning.

- **Long-Term Effectiveness Data:** From follow-up sleep studies to monitor improvements in AHI, ODI, and oxygen saturation levels over time.
- **Adverse Event Reporting:** Collection of adverse event data through vigilance reporting, clinical feedback, and ongoing monitoring.

vii) Data Analysis and Evaluation

Data collected through PMCF activities will be analyzed to:

- **Trend Analysis:** Identify any emerging patterns or trends in adverse events, device malfunctions, or therapy effectiveness.
- **Risk Assessment:** Regularly update the risk management file based on PMCF data to ensure that the benefit-risk profile remains favorable.
- **Effectiveness Monitoring:** Evaluate the long-term effectiveness of the device in reducing AHI, improving sleep quality, and enhancing patient quality of life.
- **Safety Evaluation:** Assess the incidence of adverse events such as infections, nerve damage, and discomfort.

viii) Corrective and Preventive Actions (CAPA)

If any safety concerns, performance issues, or emerging risks are identified through PMCF activities, appropriate **CAPA** will be initiated, including:

- **Root Cause Analysis** of adverse events and device malfunctions.
- **Device Modifications:** Revisions in device settings, software, or hardware design if performance improvements are needed.
- **Clinical Adjustments:** Updates to clinical management protocols or recommendations for specific patient populations.

ix) Reporting and Documentation

PMCF findings will be documented in regular **Post-Market Clinical Follow-Up Reports**, which will be submitted as part of the **Periodic Safety Update Reports (PSURs)** to regulatory authorities, such as the **Notified Body** and **EUDAMED** system. These reports will include:

- An analysis of clinical data and patient outcomes.
- A summary of adverse events and corrective actions taken.
- Recommendations for improvements based on clinical findings.

d) Reporting of Serious Incidents and Field Safety Corrective Actions

Plan Overview:

- **Objective:** Establish clear procedures for reporting serious incidents and field safety corrective actions (FSCAs) related to LunaAI.
- **Key Activities:**

  Incident Reporting: Any serious incidents will be reported to the relevant authorities within 15 days through the **EUDAMED** system, with a timeline of immediate reporting in case of death or severe injury.

  FSCAs: Immediate action will be taken if a safety risk is identified, and relevant corrective actions will be shared with both Competent Authorities and users.

  Root Cause Analysis: For each serious incident or FSCA, a detailed analysis of the root cause will be conducted, and measures to prevent recurrence will be implemented.

e) Trend Reporting

Plan Overview:

- **Objective:** Monitor and report trends based on the data collected from LunaAI's post-market use.
- **Key Activities:**

  Trend Detection: Identify statistically significant increases in the frequency or severity of incidents (including non-serious incidents or expected side effects) that may impact the device's benefit-risk balance.

  Report Frequency: Manufacturers will report these trends periodically, or upon detection of a significant issue, via the **EUDAMED system**.

  Risk Mitigation: Should trends indicate a higher-than-expected risk, preventive or corrective measures will be implemented immediately.

10. Regulatory Updates

Monitoring Changes in MDR and Relevant Standards

LunaAI will implement a systematic process to stay abreast of updates in the **EU Medical Device Regulation (MDR) 2017/745** and related standards to maintain compliance with evolving regulations and harmonized standards.

a) Key Regulatory Changes

i) MDR Updates

Monitor changes to the **MDR** through the **European Commission** and **Notified Body communications**. Key areas include updates to Annex I (General Safety and Performance Requirements), Annex II (Technical Documentation), and Annex III (Clinical Evaluation). **Harmonized Standards**: Track updates to key **ISO** standards such as **ISO 14971** (Risk Management), **ISO 13485** (Quality Management Systems), **IEC 62304** (Software Development), and **EN 60601-1** (Safety of Electrical Equipment).

ii) Updating the Strategy and Technical Documentation

- **Technical Documentation (Annex II):** Regularly review and update the technical files, including:
- **Device Description:** Ensure any changes to the device design or software are documented.
- **Risk Management Files (ISO 14971):** Update the risk management strategy based on new regulatory requirements and risk assessments from post-market data.
- **Clinical Evaluation Reports (CER)**: Revise CERs to reflect new clinical data, PMCF results, and any device modifications.
- **Labeling and Instructions for Use (IFU):** Ensure that labeling and user instructions are updated in line with any new regulatory or safety standards.

b) Product Updates

i) Incorporating Device Updates and Iterative Software Versions

Product updates for LunaAI, whether hardware or software, must follow a structured approach to ensure they meet EU MDR requirements, including potential Notified Body review for significant changes.

Update Type	Regulatory Requirement	Implementation Process
Hardware Updates	Class III devices require updates to be assessed for potential risk changes, documented in **Risk Management Files**.	Perform a **Design Impact Assessment** to evaluate safety implications.
Software Updates	Substantial software updates may require **Notified Body approval** based on classification (MDCG 2020-3).	Classify software changes as **substantial** or **non-substantial**.

Validation Testing	Follow **IEC 62304** for software updates.	Perform testing and document validation results in **Design Dossier**.

ii) Process for Software Iterations:

- **Version Control**: Maintain a clear history of all software versions in the **Software Version History Log**. Each version must be tested for safety, efficacy, and compliance.

- **Substantial Updates**: Any **substantial software changes**, such as updates affecting the core functionality (e.g., algorithm changes), must be reviewed by a Notified Body, and the technical documentation must be updated accordingly.

c) Annual Safety Reporting

i) Plan for Annual Safety Update Report (ASUR)

LunaAI, as a **Class III device**, is required by **Article 61(10)** of the **MDR** to submit an **Annual Safety Update Report (ASUR)**. This report consolidates data from the **Post-Market Surveillance (PMS)** system and addresses the safety and performance of the device.

ASUR Section	Details
Adverse Events	Document and analyze all adverse events and serious incidents.
Clinical Data	Summarize the findings from Post-Market Clinical Follow-Up (PMCF) and update risk-benefit analysis.
Risk-Benefit Analysis	Review the updated risk-benefit profile based on current safety data and new clinical insights.
Device Modifications	Document the impact of any device updates or software changes on the safety profile.

ii) Submission Process:

- Submit the ASUR to the Notified Body annually for review and approval.
- Ensure the **PMS System** captures all required data to prepare a comprehensive ASUR.
- Submit the ASUR as part of the **ongoing conformity assessment** process.

d) Continuous SSCP Updates

i) Summary of Safety and Clinical Performance (SSCP) Updates

The **Summary of Safety and Clinical Performance (SSCP)** is a critical document that must be kept up to date for **Class III implantable devices** like LunaAI. It ensures ongoing transparency to regulators, healthcare providers, and patients regarding the safety, performance, and clinical outcomes of the device.

ii) Process for Continuous SSCP Updates:

- Review **clinical data**, **adverse event reports**, and **risk management files** on an ongoing basis to ensure that the SSCP accurately reflects the current state of the device.
- Revise the SSCP following significant updates to clinical performance data, PMCF findings, or any major device updates.
- Publish the updated SSCP on **EUDAMED** as required by MDR **Annex III**.

SSCP Update Aspect	Details
Clinical Evaluation	Ensure the latest PMCF and CER findings are included in the SSCP.
Adverse Events	Document and include any adverse events in the SSCP update.
Device Modifications	Reflect any device changes (software or hardware) in the updated SSCP.

iii) Publication: Ensure the SSCP is available on **EUDAMED** for public access and **regulatory review**.

e) Cybersecurity Updates

LunaAI's cybersecurity strategy integrates periodic safety updates, risk management practices, and proactive threat mitigation measures to ensure ongoing compliance with EU MDR requirements and maintain robust device security. The following sections detail how cybersecurity is monitored, vulnerabilities are managed, and updates are implemented.

f) Threat Monitoring

i) Threat Modeling

LunaAI employs the **STRIDE Methodology** to identify and evaluate cybersecurity threats throughout the device lifecycle. This methodology ensures that risks are assessed systematically and mitigated proactively.

Threat Type	Description	Mitigation Example
Spoofing	Unauthorized access to device functionality	Use of multi-factor authentication for secure communication.
Tampering	Modification of device components or software.	Regular integrity checks on firmware and software updates.
Repudiation	Inability to trace actions back to a user or system.	Implementation of an audit trail for critical actions.
Information Disclosure	Exposure of sensitive patient or system data.	Use of encryption for data storage and transmission.
Denial of Service (DoS)	Disruption of device functionality due to resource exhaustion.	Deploy rate-limiting and timeout mechanisms for critical processes.
Elevation of Privilege	Unauthorized escalation of system privileges.	Use of role-based access controls to limit system privileges

These assessments are incorporated into the **Risk Management Plan** (aligned with ISO 14971) and guide the design of cybersecurity risk controls.

ii) Automated Monitoring

LunaAI utilizes automated tools, such as Dependabot, to monitor software dependencies for vulnerabilities. Alerts are configured to notify the development and security teams of potential risks, enabling prompt mitigation.

g) Software Bill of Materials (SBOM)

The **Software Bill of Materials (SBOM)** is an essential tool for tracking all software components, both direct and indirect, used in LunaAI. It supports transparency, enhances security, and ensures regulatory compliance.

Aspect	Implementation
SBOM Generation	Generated for every software release using the **SPDX** format.
Automation Tools	Tools like **Syft** are employed to automate the creation of SBOMs.

Updates	SBOM is updated with every software or firmware change to maintain an accurate record of dependencies
Updates	SBOM is updated with every software or firmware change to maintain an accurate record of dependencies.

h) Vulnerability Management

Proactive vulnerability management is key to ensuring LunaAI's cybersecurity resilience. Identified vulnerabilities are classified, prioritized, and addressed using structured methodologies.

Activity	Details
Monitoring	Monthly reviews of vulnerability alerts using the **Common Vulnerability Scoring System (CVSS)**.
Risk Classification	Risks are classified as Critical, High, Moderate, or Low based on their potential impact.
Incident Reporting	Cybersecurity risks are reported to users and Competent Authorities within **30 days** of detection.
Controlled Risks	Mitigations are implemented for risks deemed controlled, with priority given to high-severity risks.

i) Updates and Patches

Regular software updates and patches are critical for addressing vulnerabilities and maintaining the security of LunaAI.

Stage	Action Plan
Pre-Release Validation	Updates are validated according to **IEC 62304** to ensure they meet safety and performance standards.
Documentation	Changes are documented in a **Software Version History Log** with details on updates, testing, and risk impact.
Release Process	Updates are deployed following Notified Body guidance for substantial or minor software changes.
Post-Release Monitoring	Feedback and performance metrics are gathered to evaluate the efficacy of updates and identify potential issues.

Incident and Update Workflow: This step-by-step workflow ensures a structured approach to cybersecurity incidents and updates:

- **Detection:**

  Automated tools or manual reviews identify potential cybersecurity risks. Vulnerabilities are assessed and classified using **CVSS**.

- **Risk Assessment**

  Collaboration with the risk management team ensures all risks are evaluated for safety and performance impacts. Mitigations are planned accordingly.

- **Development and Validation:**

  Software updates and patches are developed, tested, and validated under the **IEC 62304** framework to ensure compatibility and safety.

- **Notification:**

  Users and Competent Authorities are notified within 30 days of critical risks. Notifications include interim compensatory measures and patch deployment instructions.

- **Deployment and Monitoring:**

  Updates are deployed, and post-deployment monitoring tracks their performance. The SBOM and technical documentation are updated to reflect changes.

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