PX Summary of Technical Documentation (STED)

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General Information

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Person Responsible for Regulatory Compliance (PRRC):	Mauricio Henrich
Web site:	https://www.paragit.com/EXTERNAL
Single Registration Number (SRN):	DK-MF-000036577
Device Trade Name:	ParagitPX
EMDN Code:	Z12100401 Electromyographs
Basic UDI-DI:	574400503ParagitPX6B

Technical File Contents

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Introduction

The technical documentation for the medical device, ParagitPX, and this summary document are prepared in accordance with Paragit Neurotech ApS's procedures and the requirements of Annexes II and III of the Medical Devices Regulation (EU) 2017/745 (MDR). They are presented in a clear, organized, readily searchable, and unambiguous manner.

To harmonize the documentation with evidence of conformity to the General Safety and Performance Requirements (GSPR), the technical documentation is organized in the STED format, across ten (10) annexes, which adhere to MDR requirements as follows:

Annex	Basis
Annex 1 - Device Description and Specification, Including Variants and Accessories	MDR 2017/745, Annex II, Chapter 1
Annex 2 - Information to be supplied By the Manufacturer	MDR 2017/745, Annex II, Chapter 2
Annex 3 - Design and Manufacturing Information	MDR 2017/745, Annex II, Chapter 3
Annex 4 - General Safety and Performance Requirements	MDR 2017/745, Annex II, Chapter 4
Annex 5 - Benefit-Risk Analysis and Risk Management	MDR 2017/745, Annex II, Chapter 5
Annex 6 - Product Verification and Validation	MDR 2017/745, Annex II, Chapter 6, Annex II, Chapter 6.1 section (b) all indents except indent 1 and Annex II, Chapter 6.2
Annex 7 - Pre-clinical and Clinical Data	MDR 2017/745, Annex II, Chapter 6.1 section (a), (b) indent 1: - biocompatibility, sections (c) and (d) and appropriate data defined in Annex XIV MDR 2017/745, Annex II, Chapter 6.1 (with appropriate data defined in Annex XIV)
Annex 8 - EU Declaration of Conformity	MDR 2017/745, Annex IV

Annex 9 - Technical Documentation on Post-market Surveillance	MDR 2017/745, Annex III
Annex 10 - Existing Approvals and Certificates	• Data related to previous Conformity assessments for Company, Company certificates. • Supplier's certificates, agreements, and approvals

IMPORTANT NOTE: In the annexes below answers to the following requirements are found. If a requirement is not applicable, state N/A with a justification.

Annex 1 - Device Description and Specification, Including Variants and Accessories

Device description and specification

Product or trade name and a general description of the device including its intended purpose and intended users.

Product or trade name: ParagitPX

General description:

The ParagitPX consists of the following 4 key components. Each of the key components are described below and depicted in a picture.

- **Paragit Recording Unit** (PRU): Equipped with sensors for electromyography, movement, and impedance. Housed in a small PA2200 Nylon casing containing the electronics.
- **Paragit Sleeve** (PS): A non-intrusive, textile-based sleeve with EMG sensors. Designed for wearability on upper or lower limbs, made of breathable, stretchable, and washable fabric. Available in various sizes and equipped with conductive yarn and polymer.
- **Paragit Electrode Adapter** (PEA): A 3D printed adapter for connecting the PRU to electrodes with a fixed distance.
- **Paragit Flex Adapter** (PFA): A 3D printed PA2200 adapter for flexible connection of the PRU to wired electrodes.

In addition to the key components above, the PRU can be charged with a USB-C charger which is provided by Paragit Neurotech.

Intended purpose:

ParagitPX is designed to collect signals for the investigation of processes related to muscle activity and movement (Electromyography - EMG, Movement - IMU, and skin impedance). It serves as a tool for athletes, sports enthusiasts, healthcare professionals and lay users to obtain objective and quantitative data on muscle activation, movement patterns, and impedance for research purposes only.

Intended users and patient population:

ParagitPX is intended for use by athletes, sports enthusiasts, healthcare professionals and lay users for studying muscle activity and movement. ParagitPX is used by the adult population and it applies to a broad range of users interested in understanding muscle function and movement dynamics.

Basic UDI-DI and product code, catalogue number or other unambiguous reference allowing traceability

Basic UDI-DI: 574400503ParagitPX6B

EMDN code: Z12100701 EMG TELEMETRY SYSTEMS

MDR code: MDA 0318 other active non implantable devices

SRN: DK-MF-000036577

Intended patient population and medical treated considerations such as patient selection criteria, indications, contra-indications, warnings

Indications

ParagitPX is indicated for use in any adult population not excluded by the contraindications to collect data that fosters understanding of movement and muscle activation.

Contraindications

- Not to be used by individuals allergic to materials in contact with the skin, such as polyester, nylon, and silicon.
- Not suitable for individuals with a history of severe skin irritation, open wounds, or lesions in the area of device placement.
- Not intended for use by individuals who cannot tolerate pressure or mild compression on the skin, non-cooperating individuals, or those incapable of self-dressing without caregiver support.
- The device has not been tested in pregnant or breastfeeding women; therefore, its use is contraindicated in these groups.

• The device has not been tested in users with pacemakers; therefore, its use is contraindicated in these groups.

Warnings

• Clean the skin before putting the sleeve or one of the two adapters on.
• Take off immediately in case of rash, irritation, swelling or similar.
• The device should not be used while taking a shower or exposing it to water in any other way.
• The device must not be connected to a worn while also connected to a power source or computer.
• The device should not be placed near any external electromagnetic fields during use.
• Use and store the product in accordance with conditions outlined in the Instructions for Use (Avoid exposing the device to direct sunlight or extreme heat sources, temperature and humidity as these conditions can negatively impact the performance and lifespan of the device).
• The device shall not be opened by the user and the battery is not intended to be replaced by the user.
• The main plug of the power supply (charger) is considered as a disconnecting device. During charging, do not position the device in such a way that it is difficult to operate the charger.
• Keep the AC adapter away from infants, toddlers and children.
• Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
• Use of accessories, transducers and cables other than those specified or provided by this IFU could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ParagitPX product, including cables specified by this IFU. Otherwise, degradation of the performance of this equipment could result.
• The device should not be connected to a high frequency (HF) surgical equipment and to an Electromyography or Evoked response equipment.
• The device should not be used close to a shortwave or microwave therapy equipment.

Cases that customers can expect if ParagitPX performance is lost or degraded due to electromagnetic disturbance:

• INA circuit inside PRU does not detect electromyography within acceptable SNR range.
• IMU does not record acceleration or angular rate.
• PRU does not record a minimum of 24h.
• PRU does not transmit data through physical cable attachment.
• PRU does not emit driver frequencies for evaluation of skin/electrode performance.

Potential Side effect

• The most common side effect is mild skin irritation or redness, expected to resolve after removing the device.
• In rare cases, allergic reactions to materials used in the device may occur. Immediate medical attention should be sought if signs of an allergic reaction appear.
• If discomfort or uncomfortable pressure is experienced in the area where the device is placed, users shall remove the device.

Limitations

• The device is not intended to support, suggest, or directly diagnose or monitor any disease. The system is solely intended to be used for research purposes related to muscle activation and movement.

Principles of operation of the device and its mode of action

The ParagitPX operates through a series of well-defined steps. The following are the primary operating functions:

1. **Connection to the PRU**: The PRU is the core component of the device and must be connected to either the textile sleeve or one of the adapters prior to use.
2. **Wearing the Device**: Users are required to wear the sleeve according to the instructions provided in the Instruction for Use (IFU).
3. **Data Collection**: Once the device is worn as instructed and turned on, it begins to collect and store relevant data.
4. **Data Extraction and Transfer:** Post data collection, the device is connected to a computer via a USB port.
5. **Data Visualization and Analysis**: After extracting the data, it can be uploaded for visualization to any data processing software.

The rationale for the qualification of the product as a device

Based on the definition of medical device according to MDR, Article 2: '**medical device**' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

• diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
• diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
• investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
• providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Intended purpose of ParagitPX is: ParagitPX is designed to collect signals for the investigation of processes related to muscle activity and movement (Electromyography - EMG, Movement - IMU, and skin impedance). It serves as a tool for athletes, sports enthusiasts, healthcare professionals and lay users to obtain objective and quantitative data on muscle activation, movement patterns, and impedance for research purposes only.

By definition of a medical device and the intended purpose of the ParagitPX medical device, the following components are also classified as Class I medical devices according to Annex VIII, Chapter III, Section 6, Active Devices, Rule 13 of MDR 2017/745, and MDCG 2021-24:

- **Paragit Recording Unit** (PRU).
- **Paragit Sleeve** (PS).
- **Paragit Electrode Adapter** (PEA).
- **Paragit Flex Adapter** (PFA).

Risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII of the MDR

Medical product ParagitPX is classified according to MDR 2017/745, Annex VIII: Class I, Rule 13. Further details can be found in PX Product Classification.

Classification Criteria:

Medical software ParagitPX is classified as Class A according to IEC 62304:2006/A1:2015 - Medical software - Software life cycle processes.

ParagitPX contains embedded software (firmware) that can contribute to a hazardous situation but that situation does not result in unacceptable risk (no injury or damage to health is possible) after consideration of risk control measures - therefore The ParagitPX is classified as Class A software according to IEC 62304:2006/A1:2015 - Medical device software - Software life cycle processes. Essentially, if the software fails, it will not cause any harm to the patient because the software is indicated for investigative usage only - not diagnosis or disease monitoring.

An explanation of any novel features

There are no novel features.

Description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with medical device

- USB medical charger - Medical Charger: 5V USB charger with USB to Type C cable - model: HDP05-MD05010U.
- USB - Type C cable.
- Transportation bag - Transportation bag (pouch).

Description or complete list of the various configurations/variants of the device that are intended to be made available on the market;

Required:

• **Paragit Recording Unit (PRU)**: Sensors for the acquisition of relevant bio signals encompassed in a 3D casing.

One of the following :

• **Paragit Sleeve (PS)**: Textile sleeve with dry electrode for placement on calf or forearms either forearm or calf measurement.
• **Paragit Electrode Adapter (PEA)**: Adapter to make the PRU compatible with commercially available medical-graded EMG/ECG electrodes with a set inter-electrode distance.
• **Paragit Flex Adapter (PFA)**: Adapter to make the PRU compatible with commercially available medical grade electrodes for flexible placement

General description of the key functional elements, e.g. its parts/components (including software), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. This includes labelled pictorial representations (e.g. diagrams, photographs and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

The ParagitPX consists of the following 4 key components. Each of the key components are described below and depicted in a picture.

• **Paragit Recording Unit** (PRU): Equipped with sensors for electromyography, movement, and impedance. Housed in a small PA2200 Nylon casing containing the electronics.
• **Paragit Sleeve** (PS): A non-intrusive, textile-based sleeve with EMG sensors. Designed for wearability on upper or lower limbs, made of breathable, stretchable, and washable fabric. Available in various sizes and equipped with conductive yarn and polymer.
• **Paragit Electrode Adapter** (PEA): A 3D printed adapter for connecting the PRU to electrodes with a set distance.
• **Paragit Flex Adapter** (PFA): A 3D printed PA2200 adapter for flexible connection of the PRU to wired electrodes.

In addition to the key components above, the PRU can be charged with a Medical USB-C charger which is provided and delivered by Paragit Neurotech, and a small transportation pouch is included in the package.

Description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body.

Materials in direct/ indirect contact with the human body

	Direct/indirect	Description
PS non-conductive base textile	Direct	86 % Polyamide 14 % Elastane Products do not contain latex or natural rubber or pose any harmful human impact associated with its intended use. Products do not contain human or animal tissue or extracts, prohibited azo dye pigments, medical substances or phthalates. The products are in compliance with REACH. No chemicals added during treatment/finishing. Products may contain softening and antistatic agents up to 1.5 %. The products are covered by Oeko-Tex Standard 100, class II
PS Gecko Electrodes	Direct	ElectroSkin electrodes are built

		with a biocompatible silicone surface with optimal skin-electrode impedance which enables the highest signal quality. Has passed the following: - ISO 10993-5:2009 (cytotoxicity) - ISO 10993-10:2021 (skin sensitization) - ISO 10993-23:2021 (skin irritation)	
Insulation Patch	Direct	Adhesive patch to attach the electrodes to the textile base. Has passed the following: - ISO 10993-5:2009 (cytotoxicity) - ISO 10993-10:2021 (skin sensitization) - ISO 10993-23:2021 (	

		skin irritation)
PS PhantomLink	Indirect	Conductive tape to connect the electrodes to the PRU. Has passed the following: - ISO 10993-5:2009 (cytotoxicity) - ISO 10993-10:2021 (skin sensitization) - ISO 10993-23:2021 (skin irritation)
PRU-C Casing Subsystem (plastic enclosure)	Indirect	3D printed plastic enclosure consisting of polyamide 12. Bio compatible accorting to EN ISO 10993-1 and USP/level VI/121 degrees celcius.
Data on history of clinical use or human exposure	This is the first generation of the device.	

Equipment List

No.	Equipment Name	Type	Responsible person	Reference

1.	Oscilloscope	SDS2204X Plus	Mohammad Filfil	QMS 2024-04-08 Calibration, Monitoring and Measurement List
2.	Current metre	DMM6500 6 ½ Digit Multimeter		
3.	Signal generator	Tenma 72-14111 10MHz 125MSa/s		
4.	Bench power supply	Tenma 72-2925 digital DC power supply 30V 10A		
5.	Hand multimeter	Tenma 72-7780		

Physical, Chemical and Biological Safety Statement

We declare under our sole responsibility that medical product Paragit PX, and manufacturing process guarantee the characteristics and performances referred to in Annex I (Section II) of MDR 2017/745.

Particular attention is paid to:

The choice of materials used, particularly as regards toxicity and flammability.

The compatibility between the materials used, tracking account of the intended purpose of the device. All materials used in the production of the medical product Paragit PX are referred to in Bill of Material - BOM in this document. Medical product Paragit PX doesn't incorporate, as an integral part, human blood derivatives, and doesn't incorporate tissues of animal origin. Regulation 722/2012 of 08 August 2012 introducing detailed specifications as regards the requirements laid down in MDR 2017/745 (GSPR 13.2 (Annex I)) with respect to medical devices manufactured utilising tissues of animal origin isn't applicable for medical device Paragit PX.
Technical specifications, such as features, dimensions and performance attributes, of the device and any variants /configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications. Technical specifications can be found in document Instruction for Use - ParagitPX under section 11. Technical data sheet.
Reference to previous and similar generations of the device
An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist. This is the first generation of the device.
An overview of identified similar devices available on the Union or international markets, where such devices exist. According to the Clinical evaluation report, the device was identified as equivalent to Cometa Picoblue.

Referenced documents:

- *PX Intended Purpose*
- *PX Product Classification*
- *PX Instructions For Use*

Annex 2 - Information to be supplied By the Manufacturer

Labels on the medical product and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold;

ParagitPX Label

Recording Unit

Sleeve

Electrode/Flex Adapter

Instructions for use in the languages accepted in the Member States where the device is envisaged to be sold

PX Instructions For Use is in a separate document contained in Annex 2 - Information to be supplied by the manufacturer with description for use in details.

Referenced documents:

- PX Product Label
- PX Instructions For Use
- PX Packaging Instruction

Annex 3 - Design and Manufacturing Information

Information to allow the design stages applied to the device to be understood. The overall D&D process structure is depicted in the procedure QMS Design and Development Procedure. The software lifecycle processes flowchart is depicted in the QMS Software Development.
Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. List of all components is defined through the PXS Design Output. Technical characteristics are defined in PX Instructions For Use. Suppliers are approved through QMS Supplier List. The overall Production process is described in QMS Production and Process Controls
Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed. Legal Company Name: Paragit Neurotech ApS Address: Grundtvigsvej 6a, 1864 Frederiksberg, Denmark Web site: https://www.paragit.com/ E-mail: contact@paragit.com

Referenced documents:

- *QMS Design and Development Procedure*
- *QMS Software Development*
- *QMS Production and Process Controls*
- *DDP231201-01 Design and Development Plan*
- *PX System Requirements List*
- *2024-04-03 PRU Firmware Requirements Specification*
- *PX SDP231228 Software Development Plan*
- *PX 2024-04-03 Software Architecture*
- *PX Product Configuration*
- *PX 2024-04-03 Software Configuration Record*
- *PX 2024-04-03 Software Maintenance Plan*
- *QMS Supplier List*
- *PX Instructions For Use*

Annex 4 - General Safety and Performance Requirements

The general safety and performance requirements that apply to the device and an explanation as to why others do not apply;

Complete overview of fulfilment of GSPRs is given through General Safety and Performance Requirements Checklist – ParagitPX: PX GSPR Checklist Final.

The method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

Method(s) used to demonstrate conformity with GSPRs is shown throughPX GSPR Checklist Final

All applicable standards, directives, guidelines and regulations for ParagitPX medical device are given in List of Applicable Standards and Regulations: PX 2024-04-01 List of Applicable Standards and Regulations

Referenced documents:

- *PX GSPR Checklist Final*
- *PX 2024-04-01 List of Applicable Standards and Regulations*

Annex 5 - Benefit-Risk Analysis and Risk Management

Benefit-risk analysis referred to in Sections 1 and 8 of Annex I of the MDR, solutions adopted and the results of Risk Management Process

The risk evaluation of medical product ParagitPX was performed according to QMS EN ISO 14971:2019/A11:2021 - Medical devices - Application of risk management to medical devices.

PX Annex 05 - Benefit-Risk Analysis and Risk Management contains documents needed for examination of risk. It is established throughout the life-cycle for identifying hazards associated with a medical product, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls.

The Risk Management Plan identifies the risk management activities and their scope, roles and responsibilities. It identifies criteria for the product's risk acceptability.

Risk assessment is the act of determining the probability that a risk will occur and the impact that event would have, should it occur.

As shown in the risk analysis table, after implementation of the risk-minimising actions, the identified risks are acceptable and weighted against the benefit in application.

Risk management report documents the risk management process and is intended to ensure that:

- risk management plan is implemented,
- overall residual risk is acceptable and
- suitable methods are available to get relevant information from all pre- and post-delivery phases.

ParagitPX is safe for use provided that the proper warnings in the IFU are heeded.

After all risk control measures have been implemented and verified, the Risk Management Team decides if the overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan.

All of the risks are reviewed. Risks are reduced to an acceptable level.

Solutions adopted and the results of the risk management referred to in Section 3 of Annex I of the MDR

All risks are minimised according to AFAP (As far as possible) without adversely affecting the benefit-risk ratio principle from General Safety and Performance requirements using Inherent safety by design.

In total, the risks related to use of the medical product ParagitPX are evaluated as acceptable. In consideration against the benefit the risks are justifiable.

The performance and safety of the medical product ParagitPX as claimed have been established and the risks associated with the use of the medical product are acceptable.

All risks related to use of the medical product ParagitPX and its software are evaluated as acceptable. In consideration against the benefit the risks are justifiable. After implementing control actions, all risks are categorised in low level of risk (Risk level-Acceptable).

Identified risks according to product life-cycle were evaluated by the risk management team. The decision that the product is safe for use is given. The product doesn't pose any risks for users and patients.

Referenced documents:

- QMS Risk Management
- QMS Risk Management Policy
- QMS Cybersecurity Policy
- PX 2024-04-01 Risk Management Plan
- PX 2024-04-01 Risk Analysis (product)
- PX 2024-04-01 Risk Management Report

Annex 6 - Product Verification and Validation

Results and critical analyses of all verification and validation tests and or/studies prior to final release which were undertaken to demonstrate conformity of the device with the requirements of MDR and in particular the applicable general safety and performance requirements.

This section summarized the results of verification for medical product ParagitPX undertaken to demonstrate conformity of the Product with the General Safety and Performance Requirements that apply to it.

Verification and Validation activities were planned and conducted according to plans and reports described in PX Annex 06 - Product Verification and Validation.

Final conclusions:

All test for medical product ParagitPX are finalized, and ParagitPX is performance are in accordance with its intended use as indicated in the document PX Intended Purpose for this medical product.

Status of verification and validation is Pass.

Where a device incorporates a medicinal product according to Directive 2001/83/EC, a statement indicating this fact.

N/A – ParagitPX does not incorporate medicinal products according to Directive 2001/83/EC.

Where a device is manufactured utilizing tissues or cells of human or animal origin, a statement indicating this fact.

N/A – ParagitPX is not manufactured utilizing tissues or cells of human or animal origin.

In case of devices composed of substances intended to be introduced into, absorbed by or locally dispersed in the human body, detailed information on ADME, interactions, local tolerance and toxicity

N/A – ParagitPX is not composed of such substances.

In case of devices containing CMR or endocrine-disrupting substances, a justification regarding their presence

N/A – ParagitPX does not contain CMR or endocrine-disrupting substances.
In case of devices in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps, including validation reports with respect to packaging, sterilization and maintenance of sterility N/A – ParagitPX is not sterile.
In case of devices with a measuring function, a description of the methods used in order to ensure the accuracy in the specifications N/A – ParagitPX is not a device with a measuring function.
In case of devices connected to other devices, a description of this combination/configuration including proof that it conforms to GSPR requirements N/A – ParagitPX is not connected to other devices.
physical, chemical and microbiological characterization; No additional testing needed.
electrical safety and electromagnetic compatibility; Paragit Neurotech ApS received reports from SIQ laboratory as proof to meet international standards QMS IEC 60601-1:2006/A2:2021, QMS IEC 60601-1-2:2015/A1:2021, QMS IEC 60601-2-40:2016, QMS IEC 60601-1-11:2015/A1:2020, QMS IEC 60601-1-6:2010+AMD1:2013+ AMD2:2020 and IEC 60601-2-40 , IEC 60601-1-11, ensuring its safety in the intended environment. These test are in PX Test Reports.
software verification and validation: summary results of all verification, validation and testing performed in-house and in a simulated or actual user environment prior to final release, all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer; Verification of medical software ParagitPX was conducted according to the PX 2024-04-03 Software Verification Plan, as it mentioned above, through tests described in listed software documents, PX Annex 06 - Product Verification and Validation of TF. The medical product ParagitPX verification was done through execution of tests listed in PXS ParagitPX System Traceability Matrix, Annex 6 of TF. Result of verifications for medical product is Pass and documented in the PX FVR240424 Final Verification Report. All qualification activities which are described in protocols IQ, OQ and PQ for medical software ParagitPX are successfully completed. All validation tests were successful.

Medical product ParagitPX software fulfilled its intended purpose.

Validation of the medical software ParagitPX is performed in accordance with its intended purpose as indicated in the document PX Intended Purpose.

Software Validation is performed according to the PX 2024-04-03 Software Validation Plan and documented in the PX SVR240425 Software Validation report.

stability, including shelf life;

The various components of the solution have the following product lifetimes and reusability specifications:

- The PRU, the charger, the PFA, and the PEA have product lifetimes of 3 years. Following outlined cleaning guidelines, these two components can be reused across patients.
- The PS can be reused for up to 3 months or 16 recordings of 24 hours each. The PS should not be reused across patients as this can lead to loosened electrodes and degraded performance.

The intended frequency of use is 1-4 cycles of 24 hours per month, but this should be customized by the clinician and/or researcher to fit the needs of the individual patient or trial.

performance and safety.

During verification and validation testing of the product, performance and safety of ParagitPX were confirmed.

Referenced documents:

- *PX Usability Evaluation Plan*
- *PX User Interface Specification*
- *PX Usability Participant List*
- *PXS Usability Tasks and Questionnaires*
- *PX Usability Test Overview*
- *PX Usability Test Report*
- *PX Biological Compatibility Evaluation Plan*
- *PX Biological Risk Assessment*
- *PX Literature Search Protocol*
- *PX VER240403-01 Verification Plan*
- *PX LVE240424 Label Verification Evidence*
- *PX VERPT240424 Verification Record for Packing and Transport*
- *PX FVR240424 Final Verification Report*
- *PX VAP240403 Validation Plan*
- *PX OQE240425 Operational Qualification Evidence*
- *PX PQE240425 Performance Qualification Evidence*
- *PX IQE240425 Installation Qualification Evidence*

- *PX LVA240425 Label Validation Evidence*
- *PX VARPT240425 Validation Record for Packing and Transport*
- *PX VAR240425 Final Validation Report*
- *PX 2024-04-03 Software Verification Plan*
- *PX FVR240424 Final Verification Report*
- *PX 2024-04-03 Software Validation Plan*
- *PX VAR240425 Final Validation Report*
- *PXS ParagitPX System Traceability Matrix*

Annex 7 - Pre-clinical and Clinical Data

Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;

N/A – All of the necessary tests are mentioned in other sections, no additional testing needed.

Detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular:

the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;

Paragit perform internal Biological evaluation as proof that evidence of confirmed biocompatibility that is part of Annex 06 in TF.

Clinical evaluation plan and report and its updates according to Part A of Annex XIV

PX Clinical Evaluation Report (signed) was done according to the PX Clinical Evaluation Plan (signed) for medical product ParagitPX.

PX Clinical Evaluation Report (signed) demonstrates that medical product ParagitPX conforms to the General Safety and Performance Requirements (GSPR), achieving its intended purpose without exposing users and patients to risk.

External specialist, a medical doctor, for Paragit Neurotech ApS has conducted the clinical evaluation according to the applicable requirements of the MEDDEV 2.7/1 Rev.4 and the evaluation complies with the requirements as amended in Annex XIV of the European Medical Device Regulation 2017/745.

Clinical evaluator is a specialist with sufficient practical experience, PX CER author CV.

PX Clinical Evaluation Report (signed) contains the following:

- Scope and context of the evaluation.
- The inputs (clinical data).
- The appraisal and analysis stages.

• Conclusions about the safety (implications) and performance of the device in question.

Inputs are contained in PX Literature Search Protocol (signed) which is a collection of found literature. Found literature is evaluated in the mentioned LSP document.

The intended use and corresponding risk reduction measures are adequate and the product information is suitable for the intended users and sufficiently covers all usability aspects.

There is full consistency between the clinical data, the information materials supplied by the manufacturer and the risk management documentation for the device under evaluation.

PMCF plan and evaluation report according to Part B of Annex XIV or a justification why a PMCF is not applicable

The PMCF plan has been compiled according to requirements in Annex XIV of the MDR – since this is the first revision, the PMCF evaluation report will be drawn up after collecting the anticipated information.

Referenced documents:

- PX 2024-04 Election of Clinical Evaluation Report Author
- PX 2024-04 Declaration of interests
- PX 2024-03 Clinical Evaluation Plan
- PX 2024-03 Literature Search Protocol
- PX 2024-03 Clinical Evaluation Report
- PX CER author CV
- PX PMCF240220-01 PMCF Plan

Annex 8 – EU Declaration of Conformity

Declaration of Conformity which demonstrates compliance to Annex IV of the MDR.

Referenced documents:

- *PX EU Declaration of Conformity*

Annex 9 - Technical Documentation on Post-market Surveillance

The post-market surveillance plan in accordance with Article 84 of the MDR

PMS is a collection of processes and activities used to monitor the performance of a medical product.

These activities are designed to generate information regarding use of the device to expediently identify product design and/or usage problems and accurately characterize the real-world device behavior and clinical outcomes. The need for PMS arises immediately upon commercialization of the medical product.

The document PMS Plan – ParagitPX describes activities related to the post market surveillance plan for medical product ParagitPX by Paragit Neurotech ApS.

Purpose of this document is to prepare a plan/protocol for Post Market surveillance activities.

This plan describes the responsibilities and activities of the company Paragit Neurotech ApS in the context of Post Market surveillance activities across all lifetime phases of medical product ParagitPX.

Team responsible for analysis of reports, identification of new hazards, update of Risk Management File (RMF) and Clinical Evaluation Report (CER) and finalizing PMS activities through Post Market Surveillance Report is defined in this document, ref. document PMS Plan - ParagitPX.

Post Market Surveillance Report according to Article 85 of the MDR

The document Post Market Surveillance Report – ParagitPX analyses the data gathered from various activities defined in the Post market Surveillance Plan with the aim of identifying needs for preventive, corrective or field safety corrective action and options for improving the usability, performance and safety of the products.

Also, trends are detected and corresponding documents from the TF are updated with new information, if needed.

Referenced documents:

- *PX PMSP230220-01 PMS Plan*
- *PX PMCF240220-01 PMCF Plan*

Annex 10 - Existing Approvals and Certificates

All existing approvals and certificates (Data related to previous Conformity assessments for Company, Company certificates, Supplier's certificates, agreements, and approvals)

Referenced documents:

- PX GS1 Company prefix Certificate

Revision History

The table below presents the major changes and tasks for this document.

Version	Date	Change/Action	Author
1.0	2024-04-07	Create	Nikola Stojanovic (NIST)
1.1	2024-04-22	Update	Mauricio Carlos Henrich (MAHE)
1.2	2024-04-23	Update	Mathias Stephensen (MAST)
1.3	2024-04-23	Update	Mathias Stephensen (MAST)
1.4	2024-04-25	Update	Nikola Stojanovic (NIST)
1.5	2024-04-25	Update	Nikola Stojanovic (NIST)
1.6	2024-04-25	Update	Nikola Stojanovic (NIST)
1.7	2024-04-25	Ready	Nikola Stojanovic (NIST)
1.8	2024-04-26	Update	Mathias Stephensen (MAST)
1.9	2024-04-26	Update	Mauricio Carlos Henrich (MAHE)
1.10	2024-04-26	Update	Mauricio Carlos Henrich (MAHE)
1.10	2024-04-26	TSK-1561 Reviewed	Mauricio Carlos Henrich (MAHE)
1.10	2024-04-29	TSK-1562 Reviewed	Mathias Stephensen (MAST)
2.0	2024-04-29	Publish	Mathias Stephensen (MAST)

Attached Files

The table below list the list of files which are attached to this document at the moment of export.

File Name	Upload Date	Size	SHA256

Acceptance Tasks

The table below list the accomplished Acceptance tasks for this document.

Completion Date	Version	Completed by	Method	Description

Signatures Tasks

The table below presents the accomplished Signature tasks for this document.

Completion Date	Version	Completed by	Method	Description