MDR Technical Documentation Assessment Report

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Version: 1

Report No.: %PROJECT\_ORDERNUMBER%

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***Meaning and colors of hidden text:***

* *The hidden text provides a guidance for the TD assessment.*
* *Hidden text in blue and italics is valid for all device types.*
* *Hidden text in green and italics specifies additional requirements for devices with a non-medical intended purpose (MDR, Annex XVI*

Legal manufacturer {%PROJECT\_SOLD\_TO%}

{%PROJECT\_SOLD\_TO\_ADR%}

Single registration number {%SRN\_Manufacturer%}

Authorised representative {%PROJECT\_CBW\_EU\_NAME%}

Production location(s) See Section [3.3](#_Design_and_manufacturing), Design and manufacturing sites

Test subject {%PROJECT\_CBW\_PRODUCT%}

EMDN code(s) {%EMDN%}

European Medical Device Nomenclature

MDN / MDA and MDS code(s) MDA 0315

Commission Implementing Regulation (EU) 2017/2185

Basic UDI device identifier(s) {%Basic UDI-DI(s)%}

Test specifications The General Safety and Performance Requirements of MDR Annex I;  
technical documentation in accordance with MDR, Annexes II and III; and test programmes in accordance with Section 4 of this report

Scope Technical Documentation Assessment in accordance with the Medical Device Regulation

Please select

This technical report may only be quoted in full. Any use for advertising purposes is subject to prior written authorisation.  
This report is the result of a single examination of the item in question and does not generally apply to the quality of other products in regular production.

Contents

[General Aspects 5](#_Toc256000000)

[1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES 5](#_Toc256000003)

[1.1 Device description and specification 5](#_Toc256000004)

[1.2 Previous and similar generations of the device (MDR Annex II Section 1.2) 9](#_Toc256000005)

[2. INFORMATION SUPPLIED BY THE MANUFACTURER 9](#_Toc256000006)

[2.1 Labels 10](#_Toc256000008)

[2.2 Instruction for use/ accompanying documentation 11](#_Toc256000009)

[2.3 Information for patient (and implant card) ☐ N/A 13](#_Toc256000011)

[3. DESIGN AND MANUFACTURING INFORMATION (MDR ARTICLE 10.1) 14](#_Toc256000012)

[3.1 Design stages applied (MDR Annex II Section 3(a)) 14](#_Toc256000013)

[3.2 Manufacturing process and process validation (MDR Annex II Section 3(b), Annex VII Section 4.5.3) 14](#_Toc256000014)

[3.3 Design and manufacturing sites (MDR Annex II Section 3(c)) 15](#_Toc256000015)

[4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS 15](#_Toc256000016)

[4.1 Applicable general safety and performance requirements (MDR Annex II Section 4(a)), method or methods used to demonstrate conformity (MDR Annex II Section 4(b)), harmonised standards, common specifications, or other solutions applied (MDR Articles 8, 9; MDR Annex II Section 4(c), controlled documents offering evidence of conformity (MDR Annex II Section 4(d)) 16](#_Toc256000017)

[4.2 Declaration of Conformity (MDR Art. 19, Annex IV) 17](#_Toc256000018)

[5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT (MDR ARTICLE 10.2; MDR ANNEX II SECTION 5) 17](#_Toc256000020)

[5.1 Analysis of risks due to use error (usability) 19](#_Toc256000024)

[6. PRODUCT VERIFICATION AND VALIDATION (MDR ANNEX II SECTION 6) 20](#_Toc256000026)

[6.1 Pre-clinical and clinical data (MDR Annex II Section 6.1) 20](#_Toc256000027)

[6.2 Additional information required in specific cases (MDR Annex II Section 6.2) 37](#_Toc256000028)

[7. Summary of safety and clinical performance (SSCP) (MDR Article 32) ☐ N/A 51](#_Toc256000029)

[8. Post-Market Surveillance 51](#_Toc256000033)

[8.1 Periodic Safety Update Report (PSUR) (MDR Articles 84, 85, 86; MDR Annex III) ☐ N/A 51](#_Toc256000035)

[9. Additional regulations, procedures, directives, commission decisions 51](#_Toc256000037)

[9.1 Environmental protection, safety of disposal 51](#_Toc256000038)

[9.2 Other regulatory requirements ☐ N/A 52](#_Toc256000039)

[10. Additional Surveillance Activities (ASA) (MDR Annex VII Sections 4.6, 4.8, 4.10) 52](#_Toc256000040)

[10.1 Special audit of the QM system ☐ N/A 52](#_Toc256000041)

[10.2 Items for next regular audit ☐ N/A 53](#_Toc256000042)

[10.3 Follow-up project ☐ N/A 53](#_Toc256000043)

[10.4 Recommended conditions on certification ☐ N/A 53](#_Toc256000044)

[11. Final Conclusion (MDR Annex VII Section 4.6) 53](#_Toc256000045)

[12. Version History 56](#_Toc256000048)

General Aspects

Technical documentation (TD) Structure and Content (MDR Article 10.4; MDR Annex II and III)

Technical documentation should preferably be structured in accordance with Annexes II + III.

If another structure is chosen, it would be helpful if the Client-MDR Technical Documentation Submission Checklist (ID 269323) included a list of references linking to the corresponding subsections of Annexes II/ II.

Reference the ID of the technical documentation assessed and its revision status or date. Do not include detailed content of all documents that form part of the TD, but only reference documents assessed where necessary.

ID of TD assessed: Click or tap here to enter text., Revision or date of TD assessed.

Evaluation of formal aspects

|  |  |
| --- | --- |
| The Technical Documentation is presented in a clear, organised, readily searchable and unambiguous manner | Please select |
| The Technical Documentation includes all relevant elements mentioned in Annexes II and III of the MDR | Please select |

Project management

The assessment of the technical documentation was performed for each purchase order of the legal manufacturer.

The assessment was scheduled and the required activities documented in the Project Planning Sheet (PPS). The PPS also provides information on the Product Reviewers/CLR participating in this assessment of technical documentation. For the sampled devices, the assessment was scheduled in accordance with the MDR [EC/EU Sampling Plan/Log for Product Code TDA / Planning of SSCP Validation (ID 2436)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2436) ,*(please include the version verified at the time of the assessment here; there is no need to update it in the event that newer versions of the sampling plan are available in the course of the TD assessment)* Click or tap here to enter text.

The assessment activities are summarised in this report.

Reference application ID: Click or tap here to enter text.

Reference all closed deficiency reports used in this TD assessment: Click or tap here to enter text.

|  |  |
| --- | --- |
| All deficiency reports have been closed by the product reviewers/experts/CLR. | Please select |

In case a deficiency report could not be closed with a positive recommendation, include a justification, and address the details in the corresponding assessment module and,where applicable, the conclusion and the additional surveillance activities section.

Further relevant expert reports considered during TD assessment are referenced in the respective test modules below.

# DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

## Device description and specification

Reference to documents assessed in section 1: Click or tap here to enter text.

### Product or trade name (MDR Annex II Section 1.1(a), 1.1(b))

Include the product or trade name. The product name shall be consistent with the product displayed on the products’ packaging, instructions for use and marketing brochures, the application, Appendix A/B/C, the DOC and, where applicable, the draft certificate. For sampled devices, the names have to be consistent with the [EC/EU Sampling Plan/Log for Product Code TDA / Planning of SSCP Validation (ID 2436)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2436) as well.

Product or trade name: Click or tap here to enter text.

Reference list of applicable or corresponding UDI-DIs assigned: Click or tap here to enter text.

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| Each device is assigned a Basic UDI-DI | Please select |
| The Basic UDI-DI(s) are consistent with the Appendix A/B/C | Please select |
| Each device is assigned a UDI-DI (Art. 27.1) | Please select |

### General device description, intended purpose and intended user (MDR Annex II Section 1.1(a))

Provide a general description of the device, including the intended purpose as per MDR Chapter 1 and intended user. In the case of devices with both medical and non-medical intended purposes, distinguish unambiguously between both intended purposes and intended users.

For devices without an intended medical purpose: the user of the device shall be interpreted as referring to healthcare professionals, and lay persons (Commission Implementing Regulation (EU) 2022/2346 (CS) Annex I (4.3, 9.9), CS Annex II (4i), CS Annex III (6.2), CS Annex IV (6.2), CS Annex V (6.6), CS Annex VI (2, 6.10), CS Annex VII (7.7)).

The device is: *Select all applicable properties and delete where not applicable.*

A non-active device

An active therapeutic device

An implantable device

A device intended for diagnosis and monitoring

A software

A product without medical purpose in accordance with Annex XVI

A system in accordance withArticle 22

A procedure pack in accordance with Article 22

General description of the device: Click or tap here to enter text.

Intended purpose of the device in accordance with the current instructions for use: Click or tap here to enter text.

Check consistency with Appendix A/B/C and throughout the TD.

Intended user of the device: Click or tap here to enter text.

### Intended patient population, patient selection criteria, indications, contraindications, warnings (MDR Annex II Section 1.1(c))

For Annex XVI devices, specify the group of consumers for which the device is intended. In the case of devices with both medical and non-medical intended purposes, please distinguish unambiguously between both intended patient populations and groups of consumers.

Click or tap here to enter text.

### Principles of operation of the device and its mode of action (MDR Annex II, Section 1.1(d))

Scientifically demonstrated, if necessary.  
Justification of whether it is a device according to the mode of action. Different mode of actions: Absorption, degradation

In the case of devices with both, medical and non-medical intended purposes, please distinguish unambiguously between both principles of operations and modes of actions for both intended purposes.

Click or tap here to enter text.

### Qualification of the product as a device (MDR Annex II Section 1.1(e))

|  |  |
| --- | --- |
| The product is qualified as a device under the MDR in accordance with the definition in MDR, Article 1.4. | Please select |
| If the device is a product without an intended medical purpose: is the product listed in the MDR Annex XVI? | Please select |

If none of the two above is answered with “yes”, STOP TD Assessment, inform the CARE and consider [Discontinuation of Certification, Certificate Maintenance under Condition, Withdrawal of refused Applications (ID 2559)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2559). Delete Sections 1.1.6 to 10 completely, and fill in the TDAR with a negative recommendation.

|  |  |
| --- | --- |
| If the device is a product without an intended medical purpose: does the product fall within the scope of the Common Specifications for Annex XVI devices, EU 2022/2346 (CS)? | Please select |

Include the rationale for the qualification of the product as a device, where applicable, or delete:

Rationale for the qualification of the product as a device: Click or tap here to enter text.

### Risk class of the device (MDR Annex II Section 1.1(f), Annex VIII)

The device under assessment is a device in accordance with Regulation 2017/745 of the European Parliament and of the Council on medical devices Annex VIII and the Common Specifications for the groups of products without an intended medical purpose in conjunction with the higher level classification document listed in Annex XVI of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Risk class of the device | Class IIa | Class IIb | Class IIb exempted implant | Class II implant | Class III |
| *Enter the most Relevant rule/ indent/ paragraph for the device:* |  |  |  |  |  |
| Rule: |  | | | | |
| Indent/paragraph: |  | | | | |
| Group of products in accordance with MDR, Annex XVI and Commission Implementing Regulation (EU) 2022/2346 | Click or tap here to enter text. *Annex XVI group or n/a* | | | | |

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| MDR Article 1.6: The device is correctly classified | Please select |
| MDR Annex VIII: The justification for product classification is sufficiently robust *The justification for classification is verified: there is no need to include it in this report as the justification was already reviewed and approved during application management.* | Please select |

### Novel features/ Changes to predecessor (MDR Annex II Section 1.1(g)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Provide an explanation of all novel (design) features compared to the predecessor device and document the verification of the relevant test results in Section 6 of this report, where applicable. Explain why the novel features were implemented. All novel features and changes need to be verified in a specific way: the verification/ test report(s) need(s) to provide evidence of successful and safe implementation of the specific novel feature. This is also applicable to changes and legacy devices.

Click or tap here to enter text.

Please identify every novel feature with an item number in the table below.

|  |  |
| --- | --- |
| Item No | Description of Novel Feature/ Change |
| 1 |  |
| 2 |  |

|  |  |
| --- | --- |
| Each novel feature/ change is addressed in a verification report  (reference to Section [6](#_PRODUCT_VERIFICATION_AND).) | Please select |

### Configurations and variants of the device (MDR Annex II Section 1.1(i))

List of all configurations and variants of the device intended to be made available on the marketreferenced in Section 1.1.1

Description of the main differences between the various configurations/variants: Click or tap here to enter text.

|  |  |
| --- | --- |
| The Technical Documentation covers all configurations/ variants defined in Appendix A | Please select |

### Accessories and device combinations (MDR Annex II Sections 1.1(h), 1.1(i))

Include a self-explanatory image or short description of all accessories, combinations with other products and interfaces. If relevant, list any prohibited combinations. Please indicate unambiguously which parts of the system have been assessed in this report. If no other system component was included in this assessment, please indicate this, too.

#### Accessories N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Note: Accessories provided separately need to have their own BASIC UDI-DI, labelling, instructions for use, packaging and certification! Please provide appropriate references regarding their regulatory status e.g. how and when these accessories (different Basic UDI-DI) were assessed (reference to TDAR) or will be assessed in future (reference to [EC/EU Sampling Plan/Log for Product Code TDA / Planning of SSCP Validation (ID 2436)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2436)), or which certificate covers the accessories. Manufacturers of implants in particular often regard minor accessories as non-relevant during compilation of the Technical Documentation leaving these accessories without labelling, risk management, or any of the other documents required in accordance with the MDR.

In the case of devices with both medical and non-medical intended purposse, the product configuration, including accessories, should be clearly specified for both intended purposes.

The device is used with accessories.

List of accessories provided with the device: Click or tap here to enter text.

List of accessories required for use, but not provided with the device: Click or tap here to enter text.

|  |  |
| --- | --- |
| All necessary accessories are provided with the device | Please select |
| Accessories provided with the device are also marketed separately | Please select |

#### Combined devices N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

If the device is to be connected to other device(s) in order to work as intended, a description of this combination/configuration is necessary, including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

If the device under assessment is combined with other products from the same manufacturer, please provide appropriate references regarding their regulatory status e.g., how and when these combined devices (different Basic UDI-DI) were assessed (reference to TDAR) or will be assessed in future (reference to [EC/EU Sampling Plan/Log for Product Code TDA / Planning of SSCP Validation (ID 2436)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2436)).

The device is used with other medical devices and/or other products (generic, batteries, covers, bags…) that are not medical devices and that are intended to be used in combination with it.

|  |  |
| --- | --- |
| All necessary equipment not provided with the device but intended to be used in combination with it are mentioned in the instructions for use | Please select |

List of combined devices: Click or tap here to enter text.

Include a self-explanatory image or short description of all accessories, other medical devices and other products (generic, batteries, covers, bags,…) that are not medical devices and that are intended to be used in combination with the device

### General description of the key functional elements (MDR Annex II Section 1.1(j)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Description of the key functional elements, e.g. their parts/components (including software if appropriate), their formulation, their composition, their functionality and, where relevant, their qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/ components, including sufficient explanation to understand the drawings and diagrams.

Description of key functional elements: Click or tap here to enter text.

### Materials incorporated in key functional elements (MDR Annex II Section 1.1(k)) N/A

Reviewer’s comment: This section is not applicable for medical device software as no physical materials exist for software products.

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

A 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, e.g., during extracorporeal circulation of body fluids.

This section is not intended to cover biocompatibility, chemical properties or other elements covered by Section 6 product verification.

List of materials incorporated in the key functional elements: Click or tap here to enter text. *or enter them in the table below.*

|  |  |  |
| --- | --- | --- |
| Key functional element | Materials | Body contact (direct/ indirect) |
|  |  |  |
|  |  |  |
|  |  |  |

### Technical specifications (MDR Annex II Section 1.1(l))

Technical specifications (features, dimensions and performance attributes) of the device and any variants/configurations and accessories that would typically appear in the product specifications made available to the user, e.g. in brochures, catalogues or IFUs.

In the case of devices with both, medical and non-medical intended purposes, unambiguously state the technical specifications for both

Delete as applicable

Description of final technical specification(s): Click or tap here to enter text.

Lifetime claimed: Click or tap here to enter text.

Shelf life claimed: Reviewer’s comment: This section is not applicable for medical device software.

Storage conditions: *Reviewer’s comment: This section is not applicable for medical device software.*

*(medical app / provided by download link)*.

If applicable, also include brief information on:

Preventive inspection and maintenance to be performed including the frequency of such maintenance measures for non-implantable parts

Information on microbiological state

Information on packaging

Information on sterilisation method

Information on reusable device

Information on cleaning and disinfection – how the device was designed to allow cleaning and disinfection, when the device is intended to be cleaned, disinfected or re-sterilised

Specific information on the MRI safety level of the device as far as applicable, if the device is MR Unsafe, e.g. an X-ray c-frame, this need not be mentioned. The MRI safety status is relevant for implants and carry-on/portable devices.

Please unhide if applicable:

#unhide-start

Specific Information on the MRI safety level of the device

|  |  |
| --- | --- |
| The MRI safety status of the device or system is: | MR Unsafe |
| MR Conditional |
| MR Safe |
| Untested |

Further conclusions as applicable to this assessment module on MRI safety are documented in Section 6.1.7

#unhide-end

## Previous and similar generations of the device (MDR Annex II Section 1.2)

An overview of the manufacturer’s previous generation(s) of the device, if any, or identified similar devices of the manufacturer available on the EU or international markets, where any.

Similar characteristics is to be understood as having characteristics in common, e. g. materials, design, function, intended use.

In the case of Annex XVI devices, this may also refer to analogous medical devices (CS § annex I (2.3, 8.1))

Overview of a previous generation or generations of the device: Click or tap here to enter text.

Overview of identified similar devices available on the EU or international markets: Click or tap here to enter text.

# INFORMATION SUPPLIED BY THE MANUFACTURER

(MDR ARTICLES 7, 10, 13, 16, 17, 18, 20, 27; MDR ANNEX II SECTION 2, ANNEX VI PART C; GSPR 23)

## Labels

The label(s) on the device and its packaging (single unit packaging, sales packaging, transport packaging in case of specific management conditions), shall be available in the languages accepted in the Member States where the device is envisaged to be sold; A list of EU countries in which the device is marketed and evidence of adherence to the national requirements of the languages used shall be part of the TD. If the countries in which the device is marketed have not yet been finally defined, a master template in either English or German may be acceptable (rationale: adherence to implemented procedures on translation of labels/IFUs is part of the QMS process and its surveillance and is randomly verified on-site in the course of QMS audits).

The requested labels shall be included in the TD for all device models/variants. Representative labels are accepted only if the variable information is of minor importance (e.g. dimensions, quantity of single device units included in the pack).

Labels for transport packaging are only required where the device must be transported at controlled conditions (e.g. temperature, upright, no vibration etc.).

For products without an intended medical purpose (Annex XVI), CS requirements have to be considered:

Verify that UDI carriers are placed on the label of the device and all higher levels of packaging for

Class III devices and implants by 26 May 2021

Class IIa, IIb devices by 26 May 2023.

Verify that the CE marking is in conformity with the format defined in the MDR Annex V.

List of EU countries in which the device is marketed and evidence that the national requirements of the languages used are provided: Click or tap here to enter text.

|  |  |
| --- | --- |
| Labels have been provided in all languages necessary: | Please select |
| Labels have been provided as a master label in Click or tap here to enter text. the language used during initial certification. | Please select |

Delete where not applicable

#delete-start

Refer to the action item for the next audit in Section 10 to verify the translation process for information provided by the manufacturer (as labels and IfUs). Click or tap here to enter text.

#delete-end

**Reference of labels assessed:** *If the full set of labels is provided in the TD, indicate which labels have been used for assessment: Delete, where not applicable*

Labels placed on the device and/or direct marking: Click or tap here to enter text.

Labels on sterile packaging: Reviewer’s comment: This section is not applicable for medical device software.

Labels on single-unit sales packaging: Reviewer’s comment: This section is not applicable for medical device software.

**Labels on further sales packaging (e.g. multi-pack units):** Click or tap here to enter text.

Conclusion

In the following tables, the GSPRs shall be completed. All subsections of the GSPRs are added as hidden text/guidance and can be filled in.

|  |  |
| --- | --- |
| **Requirement Annex I, 23.1, 23.2** |  |
| **GSPR 23.1**: General requirements regarding the information supplied by the manufacturer:  Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, and shall, if the manufacturer has a website, be made available and kept up to date on the website, taking into account Sections 23.1 (a) to (c). | **Please select** |
| **GSPR 23.1 (h):** Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device. | **Please select** |
| **GSPR 23.2:** Information on the label  The label bear all of the following particulars; | **Please select** |
| **(a)** the name or trade name of the device; | **Please select** |
| **(b)** the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; | **Please select** |
| **(c)** the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business; | **Please select** |
| **(d)** if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative; | **Please select** |
| (e) where applicable, an indication that the device contains or incorporates: | **Please select** |
| a medicinal substance, including a human blood or plasma derivative, or | **Please select** |
| tissues or cells, or their derivatives, of human origin, or | **Please select** |
| tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012; | **Please select** |
| **(f)** where applicable, information labelled in accordance with Section 10.4.5.; | **Please select** |
| **(g)** the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; | **Please select** |
| **(h)** the UDI carrier referred to in Article 27(4) and Part C of Annex VII; | **Please select** |
| **(i)** an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant; | **Please select** |
| **(j)** where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable; | **Please select** |
| **(k)** an indication of any special storage and/or handling condition that applies; | **Please select** |
| **(l)** if the device is supplied sterile, an indication of its sterile state and the sterilisation method; | **Please select** |
| **(m)** warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users; | **Please select** |
| **(n)** if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union; | **Please select** |
| **(o)** if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles; | **Please select** |
| **(p)** if the device is custom-made, the words ‘custom-made device'; | **Please select** |
| **(q)** an indication that the device is a medical device. If the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation'; | **Please select** |
| **(r)** in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action; | **Please select** |
| **(s)** for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

In case of packaging that does not maintain the sterile condition of the device, delete the following table:

|  |  |
| --- | --- |
| **Requirement Annex I 23.3** |  |
| **GSPR 23.3** Information on the packaging which maintains the sterile condition of a device (‘sterile packaging'):  The following particulars shall appear on the sterile packaging: | **Please select** |
| **(a)** an indication permitting the sterile packaging to be recognised as such, | **Please select** |
| **(b)** a declaration that the device is in a sterile condition, | **Please select** |
| **(c)** the method of sterilisation, | **Please select** |
| **(d)** the name and address of the manufacturer, | **Please select** |
| **(e)** a description of the device, | **Please select** |
| **(f)** if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations', | **Please select** |
| **(g)** if the device is custom-made, the words ‘custom-made device', | **Please select** |
| **(h)**the month and year of manufacture, | **Please select** |
| **(i)** an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and | **Please select** |
| **(j)** an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. | **Please select** |
| **MDR Article 10.11:** The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient. | **Please select** |
| **MDR Article 7:** The labels and markings on the device and on the packaging do not mislead the user or patient with regard to the device´s intended purpose, safety and performance. | **Please select** |
| **MDR Article 20.3**: The CE marking shall also appear in any instructions for use and on any sales packaging. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

## Instruction for use/ accompanying documentation

The instructions for use shall be available in the languages accepted in the Member States where the device is envisaged to be sold. Consider also lay users when verifying the IfU.

For products without an intended medical purpose (Annex XVI,) CS requirements have to be considered:

Reference to current instructions for use:Click or tap here to enter text.**,** and version or date Click or tap here to enter text.

|  |  |
| --- | --- |
| IfUs have been provided in all languages necessary  If “No”: Available languages: Click or tap here to enter text. | Please select |
| The IfU has been provided as an approved master template in Click or tap here to enter text. language during initial certification. | Please select |

The IfU has been verified in Click or tap here to enter text. language.

Also check manuals of separately available accessories and verify e.g. device operating manuals, surgical techniques, physicians’, patients’ or other users’ handbooks, promotional materials making specific claims related to the device.

Delete where not applicable:

Additional accompanying documents *Include accompanying document´s ID or justification where not applicable*  Click or tap here to enter text.

Conclusion as applicable for this assessment module

In the following tables, the general GSPRs shall be completed. All subsections of the GSPRs are added as hidden text/ guidance and can be filled in.

|  |  |
| --- | --- |
| **Requirement Annex I 14,1, 21.3, 23.1, 23.4** |  |
| **GSPR 14.1:** If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection | **Please select** |
| **GSPR 21.3:** The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and as appropriate, the patient. | **Please select** |
| **GSPR 23.1:** General requirements regarding the information supplied by the manufacturer:  Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate.  Such information may appear on the device itself, on the packaging … and shall take into account Sections 23.1 (a), (d) to (h). | **Please select** |
| **GSPR 23.1(d):** Instructions for use shall be provided together with devices. By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this Section | **Please select** |
| **GSPR 23.1 (h):** Where appropriate, the information supplied by the manufacturer shall take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no harmonised standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device. | **Please select** |
| **GSPR 23.1:** Such information shall, if the manufacturer has a website, be made available and kept up to date on the website: | Link to website: |
| **GSPR 23.4:** Information in the instructions for use: The instructions for use contain all of the following particulars: (a) to (ab) | **Please select** |
| **(a)** the particulars referred to in points (a), (c), (e), (f), (k), (l), (n) and (r) of Annex I, Section 23.2; | **Please select** |
| **(b)** the device's intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate; | **Please select** |
| **(c)** where applicable, a specification of the clinical benefits to be expected. | **Please select** |
| **(d)** where applicable, links to the summary of safety and clinical performance referred to in Article 32; | **Please select** |
| **(e)** the performance characteristics of the device; | **Please select** |
| **(f)** where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories; | **Please select** |
| **(g)** any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard; | **Please select** |
| **(h)** specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it; | **Please select** |
| **(i)** details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection; | **Please select** |
| **(j)** any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons; | **Please select** |
| **(k)** the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: | **Please select** |
| details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection | **Please select** |
| identification of any consumable components and how to replace them, | **Please select** |
| information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and | **Please select** |
| methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices; | **Please select** |
| **(l)** if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use; | **Please select** |
| (m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation; | **Please select** |
| **(n)** if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses; | **Please select** |
| **(o)** an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements; | **Please select** |
| **(p)** if the device bears an indication that it is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. no instructions for use are required, this information shall be made available to the user upon request; | **Please select** |
| **(q)** for devices intended for use together with other devices and/or general purpose equipment: | **Please select** |
| information to identify such devices or equipment, in order to obtain a safe combination, and/or | **Please select** |
| information on any known restrictions to combinations of devices and equipment; | **Please select** |
| **(r)** if the device emits radiation for medical purposes: | **Please select** |
| detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation, | **Please select** |
| the means of protecting the patient, user, or other person from unintended radiation during use of the device; | **Please select** |
| (s) information that allows the user and/or patient to be informed of any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. That information shall, where relevant, allow the user to brief the patient about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device. The information shall cover, where appropriate: | **Please select** |
| * warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety, | **Please select** |
| warnings, precautions and/or measures to be taken as regards the exposure to reasonably foreseeable external influences or envi­ronmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature, | **Please select** |
| warnings, precautions and/or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment, | **Please select** |
| if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered, | **Please select** |
| warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and | **Please select** |
| precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user; | **Please select** |
| **(t)** in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra-indications, undesirable side-effects and risks relating to overdose; | **Please select** |
| **(u)** in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed; | **Please select** |
| **(v)** warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information shall cover, where appropriate: | **Please select** |
| infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and | **Please select** |
| physical hazards such as from sharps. | **Please select** |
| If in accordance with the point (d) of Section 23.1 no instructions for use are required, this information shall be made available to the user upon request; | **Please select** |
| **(w)** for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional; | **Please select** |
| **(x)** for the devices covered by this Regulation pursuant to Article 1(2), information regarding the absence of a clinical benefit and the risks related to use of the device; | **Please select** |
| **(y)** date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use; | **Please select** |
| **(z)** a notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established; | **Please select** |
| **(aa)** information to be supplied to the patient with an implanted device in accordance with Article 18; | **Please select** |
| **(ab)** for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | **Please select** |
| **MDR Article 7:** The information provided in the IFU and in accompanying documents do not mislead the user or patient with regard to device’s intended purpose, safety, performance. | **Please select** |
| **MDR Article 20.3**: The CE marking shall also appear in any instructions for use and on any sales packaging. | **Please select** |
| A ccompanying documentation provides all relevant information | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### E-Labelling (Regulation (EU) 221/2226) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

E-Labelling is only allowed where the devices and accessories are intended for exclusive use by professional users (excepted software) and where use by other persons is not reasonably foreseeable for the following devices as per Regulation EU (No) 221/2226, which repeals Regulation (EU) No 207/2012 mentioned in GSPR 23.1(f):

implantable and active implantable medical devices and their accessories covered,

fixed installed medical devices and their accessories covered,

medical devices and their accessories that are fitted with a built-in system visually displaying the instructions for use.

software covered (also for lay user)

E-labelling can be provided in addition to a paper IFU for all other devices except for Annex XVI devices.

If the system to establish eIFU has not yet been approved, please include an additional surveillance activity to verify that all requirements of EU Regulation (No) 221/2226 are fulfilled.

Reference to documents assessed for E-Labelling (Document ID no or section of TD): Click or tap here to enter text.

|  |  |
| --- | --- |
| **GSPR 23.1(f):** Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012, or in any subsequent implementing rules adopted pursuant to this Regulation. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

## Information for patient (and implant card) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Under MDR Article 18.1 (a), MDCG 2019-8 and MDCG 2021-11, the manufacturer of an implantable device shall provide together with the device, the following information on the implant card permitting identification of the device:

device name,

device type,

serial number or, where applicable, lot number,

UDI; the UDI as AIDC (automatic identification and data capture) format (e.g. linear or 2D-barcodes) and the UDI-DI as HRI (human-readable interpretation);

name and address of the manufacturer, and

website of the manufacturer.

The following blank fields to be completed by the implanting healthcare institution or healthcare provider shall be given on the implant card:

name of the patient or patient ID

name and address of the health institution which performed the implantation

date of implantation.

MDCG 2019-8 gives guidance on the use of symbols recommended for the implant card as well as on implantable components that might be replaced.

An informative instruction leaflet on how to complete the IC and explain the symbols used is recommended in MDCG 2019-8.

|  |  |
| --- | --- |
| The device is an implantable device | NO |

|  |  |
| --- | --- |
| MDR Article 18: The manufacturer provides information to the patient relevant to the implantable device  Include documented evidence or justification when n/a | N/A |

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| **GSPR 23.4 (aa)** Information to be supplied to the patient with an implanted device in accordance with Article 18; | **Please select** |
| **MDR Article 7:** The information (e.g. patient information, implant card, website) does not mislead the user or patient with regard to the device’s intended purpose, safety, performance. | **Please select** |
| **MDR Article 10.11:** The manufacturer has fulfilled the language requirements of the member states where the device is to be placed on the market | **Please select** |
| **MDR Article 18.** The implant card includes all information required by the MDR Article 18, the MDCG 2019-8 guideline, and by applicable standards | **Please select** |
| **MDCG 2019-8:** The implant card includes a device type as listed in MDCG 2021-11. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

# DESIGN AND MANUFACTURING INFORMATION (MDR ARTICLE 10.1)

## Design stages applied (MDR Annex II Section 3(a))

Information to allow the design stages applied to the device to be understood.

This information may be on the specific design stages applied by the manufacturer, and/or the techniques that are used to control, monitor and verify the design of the device under assessment in these stages.

A summary of the design process with reference to the applied implemented documented procedure(s) and versions shall be included in the TD. Please take into account that reference to the design procedure alone is not sufficient. A brief description of the design stages applied is necessary also for legacy devices

Reference to documents assessed for design stages applied (Document ID No or section of TD): Click or tap here to enter text.

Description of design stages applied to the device: Click or tap here to enter text.

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| The Information on design stages applied are provided and can be followed | Please select |

## Manufacturing process and process validation (MDR Annex II Section 3(b), Annex VII Section 4.5.3)

The following data shall be fully included in the technical documentation (data do not need to be copied into this report): complete information and specifications, including the manufacturing processes and their validation, their adjuvants, if any, continuous monitoring and final product testing.

For further details, refer to the current version of the Team NB Position Paper: Best Practice Guidance for the Submission of technical documentation under Annexes II and III of the Medical Device Regulation (EU) 2017/745.

Manufacturing includes production, assembly, packaging, sterile packaging, sterilisation and final packaging (as applicable).

Reference to documents assessed for manufacturing process and process validation (Document ID No or section of TD): Click or tap here to enter text.

Short description or flowchart of manufacturing processes applied to the device: Click or tap here to enter text.

Brief description of environmental conditions used for the relevant manufacturing steps of sterile devices or devices with defined microbiological condition: Click or tap here to enter text. *or refer to Sections 6.2.9 and/or 6.2.10.*

Brief description of techniques that are used to control, monitor and verify the final device: Click or tap here to enter text.

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| The information and specifications of manufacturing processes and their validation are complete. | Please select |
| Annex VII 4.5.3: the specifications for incoming testing of critical material/components, in-process controls, and final product testing are provided in the technical documentation. | Please select |
| A complete overview of adjuvants utilised in manufacturing processes is provided in the technical documentation. | Please select |

## Design and manufacturing sites (MDR Annex II Section 3(c))

Identification of all sites, including critical suppliers and sub-contractors, where design and manufacturing activities are performed along with the service/material supplied by each.

In the case of sub-contracted (outsourced) processes:

for non-critical component suppliers (e.g. bulk), identification of supplier only   
(see also Annex II 3(c)).

for critical component suppliers (e.g. outsourced manufacturing of sterile device/implants) overview of manufacturing processes and corresponding control measures (e. g. references to verification and validation activities; copy of the certificate shall be included);

verify that the critical suppliers/sub-contractors included in the TD correlate to those listed in Appendix A/B/C; verify that the justification for (not) including the supplier in a special/next audit listed in the critical supplier tab of the current Appendix A/B/C is still correct; and where changes are needed, add an appropriate surveillance activity in this report and inform CARE. Criteria for supplier control are described in [Audit Performance and Audit-Project Closure (ID 2455)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2455) and [Audit Planning (ID 2456)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2456).

Reference list of all design & development sites: Click or tap here to enter text.

Reference list of all manufacturing sites: Click or tap here to enter text.

Reference list of all critical suppliers and sub-contractors where design and manufacturing steps are performed: Click or tap here to enter text.

Reference where information for certificates of the suppliers/subcontractors can be found in the TD: Click or tap here to enter text.

Conclusion as applicable for this assessment module

|  |  |  |
| --- | --- | --- |
| A complete overview of design and manufacturing sites, including subcontractors if applicable, is provided in the Technical Documentation | | Please select |
| The list of design and manufacturing sites and of critical suppliers and subcontractors is consistent with the ones provided in Appendix A/B/C. | | Please select |
| Certificates have been provided to demonstrate that the services provided by all manufacturers and critical suppliers are either controlled by competent authorities/accredited organisations or otherwise qualified. | Please select | |
| The justification for (non-)auditing of critical suppliers/subcontractors documented in Appendix A/B/C is correct.*.* | Please select | |
| MDR Annex II Section 6.1(b): tests performed by external laboratories for substances in accordance with Directive 2004/10/EC are under the control by a competent authority (GLP). | Please select | |

# GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

Check for rationales in case of non-applicable GSPRs.

For in-depth assessment of the general safety and performance requirements use PPP NAM AMP MDR General Requirements and all applicable device/ technology-specific PPPs.

In case of non-availability of a GSPR Checklist, other documents such as risk management, design verification, etc. to fulfil the GSPR might be acceptable, if a cross-reference is available.

To assess conformity with the General Safety and Performance Requirements according to Annex I of the Medical Device Regulation (MDR) the following TÜV SÜD Product Service test programmes (PPP) were used:

|  |  |
| --- | --- |
| TÜV SÜD Product Service Test programme (PPP General Requirements): | Revision |
| [PPP NAM AMP MDR General Requirements](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=60311) |  |
| TÜV SÜD Product Service Test programme (PPP´s device/technology specific):  List further applicable PPPs and unhide the hidden text | Revision |
| Test Program AMP MD 1111 MDS 7010 MDA 0315 MDS 1009 Medical Telemedical Networks Software PPP #/ Title |  |
| PPP AMP MDR Cybersecurity PPP #/ Title |  |

Restrictions to these test programmes are documented in this report addressing (non-)applicability of the respective assessment modules in Section 6.

## Applicable general safety and performance requirements (MDR Annex II Section 4(a)), method or methods used to demonstrate conformity (MDR Annex II Section 4(b)), harmonised standards, common specifications, or other solutions applied (MDR Articles 8, 9; MDR Annex II Section 4(c), controlled documents offering evidence of conformity (MDR Annex II Section 4(d))

The manufacturer shows compliance with the General Safety and Performance Requirements by means of the following record: e.g. a GSPR -Checklist. Multiple lists may be applicable if multiple devices are to be certified. In the case of accessories which are marketed individually, separate proof needs to be provided. Verify that all devices in the scope (refer to Section 1.1.91.1) are covered.

Devices with both a medical and a non-medical intended purpose shall cumulatively fulfil the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose (MDR Art. 1 (3)).

The manufacturer shows compliance with the General Safety and Performance Requirements by means of the following records *(include version or issue date of the referenced record)*: Click or tap here to enter text.

Verify the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS, MDCG or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full TD and, if applicable, the summary of TD.

Verify that the available Common Specifications (CS), guidance, harmonised standards, Eur. Pharm, non-harmonised standards, common technology standards, procedures for non-standardised methods and, where applicable, their validation etc. which have been applied, are documented e.g in the GSPR list or an additional list of applicable requirements. Verify that the requirements mentioned in the applicable PPPs are taken into consideration, even, if the manufacturer did not apply them (Annex VII 4.5.1).

For Annex XVI devices the state of the art and, in particular the existing harmonised standards or common specifications for analogous medical devices, based on similar technology, shall be taken into consideration (MDR § 1 (2))

Check if a gap analysis is provided in case the manufacturer applied inputs which have been revised in the meantime.

Check which methods have been used to show compliance (verification or validation) and document them in Section 6. If a non-standardised method is used, verify that said method is validated.

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| All applicable General Safety and Performance Requirements are identified and recorded as (partially) fulfilled. In case certain requirements do not need to be considered or are not applicable or partially applied, a rationale is provided by the manufacturer | Please select |
| Demonstration of conformity includes precise identification of the controlled documents offering evidence of conformity with harmonised standards, Common Specifications, MDCG or other methods employed to demonstrate conformity with the General Safety and Performance Requirements. A cross-reference to the location of such evidence is provided in the Technical Documentation and, if applicable in the summary of Technical Documentation. | Please select |
| A gap analysis for Common Specifications, MDCG guidance, harmonised standards, standards, Eur Pharm, etc. and an acceptable plan for implementation have been provided. | Please select |
| The methods used to demonstrate conformity with the requirements and documented evidence for conformity with each of these methods are adequate. | Please select |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

## Declaration of Conformity (MDR Art. 19, Annex IV)

The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The EU declaration of conformity shall be translated into an official EU language or languages required by the Member State(s) in which the device is made available.

A list of EU countries in which the device is marketed and evidence of adherence to the national requirements of the languages used shall be part of the TD. If the countries in which the device is marketed have not yet been finally defined a master template in either English or German may be acceptable (rationale: adherence to implemented procedures on translation of labels/ IFU/ DoC is part of the QMS process and its surveillance and is randomly verified on-site in the course of QMS audits).

The EU declaration of conformity shall, as a minimum, contain all the following information set out in Annex IV:

1. Name, registered trade name or registered trademark and, if already issued, the SRN of the manufacturer, as referred to in Article 31;, , its authorised representative, where applicable; and the address of their registered place of business where they can be contacted and where their location can be established;
2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The Basic UDI-DI as referred to in Part C of Annex VI;
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;
5. Risk class of the device in accordance with the rules set out in Annex VIII;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, where applicable, with any other relevant EU legislation that provides for the issuing of an EU declaration of conformity;
7. References to any CS used in relation to which conformity is declared;  
   Note:, harmonised standards do not currently need to be added to the DoC.
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
9. Where applicable, additional information;
10. Place and date of issue of the declaration, name and function of the signatory as well as an indication of the name of the individual for, and on behalf of whom, that signature was given.

Reference to EU Declaration of Conformity assessed: Click or tap here to enter text.

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| The draft DoC fulfils the requirements of MDR, Annex IV | Please select |
| The draft DoC covers all devices listed in Section 1.1.8 of this report. | Please select |

# BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT (MDR ARTICLE 10.2; MDR ANNEX II SECTION 5)

GSPR 3: The manufacturer provided the following risk management documents in the technical documentation: Click or tap here to enter text.

Include all risk management documents provided by the manufacturer relevant for this assessment

MDR Annex II Section 5(a): The benefit-risk analysis is provided in the following document:   
Click or tap here to enter text.

MDR Annex II Section 5(b): Solutions adopted are documented in the following report or report sections: Click or tap here to enter text.

Solutions adopted are risk mitigation measures. Include reference to this risk analysis section, e.g. if the risk analysis is provided as a single document

Risk categories defined: Click or tap here to enter text.

Check if the risk management file (including a chapter on or reference to benefit-risk analysis) and reference to current EN ISO 14971 is available.

For in-depth assessment of the general safety and performance requirements please consider applicable PPPs

Reference of residual risk statement provided by the manufacturer: Click or tap here to enter text.

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| **GSPR 2:** The requirement in this Annex to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.. | **Please select** |
| **GSPR 3(a):** Manufacturers shall establish a risk management plan for each device; | **Please select** |
| **GSPR 3(b):** Manufacturers shall identify and analyse the known and foreseeable hazards associated with each device; | **Please select** |
| **GSPR 3(c):** Manufacturers shall estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse. | **Please select** |
| **GSPR 3(d):** Manufacturers shall eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4 of Annex I; | **Please select** |
| **GSPR 3(e):** Manufacturers shall evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and | **Please select** |
| **GSPR 3(f):** Manufacturers shall, based on the evaluation of the impact of the information referred to in point GSPR 3(e), if necessary amend control measures in line with the requirements of Section 4 | **Please select** |
| **GSPR 4:** Risk control measures adopted by manufacturers for the design and manufacture shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority: | **Please select** |
| **GSPR 4(a):** eliminate or reduce risks as far as possible through safe design and manufacture;. | **Please select** |
| **GSPR 4(b):** where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;. | **Please select** |
| **GSPR 4(c):** provide information for safety (warnings, precautions, contra-indications) and, where appropriate, training to users. | **Please select** |
|  |  |
|  |  |
| **GSPR 8:** All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. | **Please select** |
| For products without an intended medical purpose (Annex XVI) the risk control measures according to the CS general part and CS specific Annexes are followed and implemented | **Please select** |
| **GSPR 9:** For the devices referred to in Annex XVI, the general safety requirements set out in MDR Annex I, Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. | **Please select** |
| **MDR Annex VII Section 4.5.1:** Risk control measures adopted by the manufacturer for the design and construction are considered in the pre-clinical testing.  Verify that the risk control measures mentioned in the risk management documentation, are consistent with the methods provided in section 5. | **Please select** |
| **MDR Annex VII Section 4.5.1**: The appraisal of risk management results and analysis of the pre-clinical data are considered in the clinical evaluation.  If, [Clinical Evaluation Assessment Report (CEAR) (ID 2487)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2487) is used in this project, the risk management results and analysis are considered in the clinical evaluation. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

## Analysis of risks due to use error (usability)

Reference documents regarding use error risks (Document ID no or section of TD): Click or tap here to enter text.

Include Usability Engineering & Risk Management Documents on use error risks provided by the manufacturer here, check if the usability standard EN 62366:2015 has been applied.

Include information on additionally provided documented evidence related to this section. Documents need to be identifiable and their content should be described in keywords in this section.

The following key assumptions made as the basis for acceptance/verification have been challenged to show compliance with the manufacturer´s specification and General Safety and Performance Requirements including evaluation of requirements based on the state of the art. *Standards in accordance with PPP, if applicable, or alternative methods.* The manufacturer provided sufficient and acceptable rationales: *Click or tap here to enter text.*

Where additional surveillance activities have been recommended by the expert, please copy them and the justifications thereof 1:1 into section 10 of this report.

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| **GSPR 4**: Risk control measures adopted by manufacturers for the design and manufacture of the device shall conform to safety principles, taking account of the generally acknowledged state of the art. | **Please select** |
| **GSPR 5(a):** In eliminating or reducing risks related to use error, the manufacturer shall reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and; | **Please select** |
| **GSPR 5(b):** In eliminating or reducing risks related to use error, the manufacturer shall give consideration to the technical knowledge, experience, education, training and use environment, where applicable | **Please select** |
| **GSPR 5(b):** In eliminating or reducing risks related to use error, the manufacturer shall give consideration to the medical and physical conditions of intended users (design for lay, professional, disabled or other users).. | **Please select** |
| For the devices without an intended medical purpose (Annex XVI), the manufacturer shall give consideration to the degree to which users and consumers commonly understand the risks linked to the use of the device in order to effectively reduce risks. | **Please select** |
| **GSPR 22.1:** Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment; | **Please select** |
| **GSPR 22.2:** Devices for use by lay persons shall be designed and manufactured in such a way as to: |  |
| * ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information, | **Please select** |
| * reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and | **Please select** |
| * reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results; | **Please select** |
| **GSPR 22.3:** Devices for use by lay persons shall, where appropriate, include a procedure by which the lay person: |  |
| * can verify that, at the time of use, the device will perform as intended by the manufacturer, and | **Please select** |
| * if applicable, is warned if the device has failed to provide a valid result | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

# PRODUCT VERIFICATION AND VALIDATION (MDR ANNEX II SECTION 6)

The technical documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of the MDR and the applicable general safety and performance requirements (GSPR).

It shall include results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device under consideration of its intended purpose or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications, as well as detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions.

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) shall be demonstrated. MDR Annex II Section 6.1(b) requires all tests for such chemical substances performed by external laboratories to be under the control of a competent authority. Laboratories used for such tests need to conform to GLP (Good Laboratory Practice).  
List tests that were performed at such laboratories.

For in-depth assessment of the general safety and performance requirements use PPP, NAM, AMP, MDR General Requirements and all applicable device/ technology-specific PPP´s and verify them against the methods mentioned in the GSPR list (if applicable). Also check whether the manufacturer applied the related risk measures.

Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. This is acceptable as long as the state of the art is kept.

## Pre-clinical and clinical data (MDR Annex II Section 6.1)

### Animal studies (MDR Annex II Section 6.1(a))

Reviewer’s comment: Not applicable, the product under assessment is a medical device software.

Animal studies are mainly part of the clinical assessment and are documented in the [Clinical Evaluation Assessment Report (CEAR) (ID 2487)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2487). In rare cases, e.g. additional mechanical or other tests may be performed on animals. Please include any such studies here.

See Section [6.1.14](#_Clinical_data,_Clinical) Clinical Evaluation and the assessment report referenced there.

Unhide if applicable:

#unhide start

Reference to documents assessed considering animal studies (Document ID no or section of TD): Click or tap here to enter text.

*Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications*: *n/a*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10**Fehler! Linkreferenz ungültig.** of this report.

|  |  |
| --- | --- |
| The results obtained and conclusions drawn support, and provide evidence of compliance with the design specifications and performances claimed. | **Please select** |

Conclusion as applicable to this test module

|  |  |
| --- | --- |
| **GSPR 10.1:** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. | **N/A** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: n/a

#unhide end

### Simulated use test (MDR Annex II Section 6.1(a)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Simulated use is considered to be testing in an environment simulating e.g. the patient for instance or tests performed to prove the usability of the device (Section 5.1)

See Section 6.1.13 Performance and Safety.

*Unhide if applicable:*

#unhide-start

Reference to documents assessed considering simulated use (Document ID no or section of TD): Click or tap here to enter text.

Proof of compliance with the manufacturer´s specifications and General Safety and Performance Requirements, including evaluation of requirements based on the state of the art was requested for the following key assumptions made as the basis for acceptance/verification. Standards in accordance with PPP, if applicable or alternative methods. The manufacturer provided sufficient and acceptable rationales: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 1010 of this report.

|  |  |
| --- | --- |
| The results obtained and conclusions drawn support and provide evidence of compliance with the design specifications and performances claimed. | **Please select** |

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 10.1:** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled**.** | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

#unhide-end

### Biocompatibility of the device (MDR Annex II Section 6.1(b))

Reviewer’s comment: Not applicable, the product under assessment is a medical device software.

Verify all materials in direct or indirect contact with the device (including adjuvants) and consider the identification of the materials in Section 1.1.111.1.11.

Classification according to EN ISO 10993-1 Table A1, nature of body contact

|  |  |
| --- | --- |
| Surface device | N/A |
| External communicating devices | N/A |
| Implantable devices | N/A |
| Contact duration | N/A |

~~If the assessment module was not assessed by an E-BC, please complete the following section.~~

~~#delete-start~~

~~Reference to Biological evaluation report (BER): Click or tap here to enter text.~~

~~MDR Annex VII, 4.5.4: The notified body’s assessment of pre-clinical evaluation procedures and documentation shall address the results of literature searches and any validation, verification and testing performed as well as conclusions drawn. It shall typically include consideration of the use of alternative materials and substances and take account of the packaging and stability, including shelf life, of the finished device. Where no new testing has been undertaken by a manufacturer or where there are deviations from procedures, the notified body in question shall critically examine the justification presented by the manufacturer.~~

~~Proof of compliance with the manufacturer´s specifications and General Safety and Performance Requirements, including evaluation of requirements based on the state of the art, was requested for the following key assumptions made as the basic for acceptance/verification.~~ *~~Standards in accordance with PPP, if applicable or alternative methods.~~*

~~The manufacturer provided sufficient and acceptable rationales: Click or tap here to enter text.~~

~~In case an additional surveillance was recommended, please copy them and the justifications thereof verbatim into Section 10 of this report.~~

~~#delete-end~~

~~If the assessment module was assessed by an E-BC.~~

~~#delete-start~~

~~This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.~~

~~The expert concluded:~~ *~~Please copy the conclusion of the expert report verbatim:~~* ~~Click or tap here to enter text.~~

~~The statement on fulfilment of GSPRs and conclusion drawn by the expert is shown below:~~ *~~Please copy the GSPRs of the expert report verbatim in the evaluation table below.~~*

~~In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. If no ASA is recommended, please delete the following sentence~~*~~:~~*

~~#delete-end~~

~~#unhide-start~~

~~This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis are included in~~ [~~State-of-the-art Assessment for EU Regulations (ID 96777)~~](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) ~~or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.~~

~~Reference to expert report in accordance with EC Directive: Click or tap here to enter text.~~

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~~#unhide-end~~

**~~Conclusions as applicable for this assessment module~~**

|  |  |
| --- | --- |
| **~~GSPR 10.1:~~** ~~Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to:~~ | **~~Please select~~** |
| **~~GSPR 10.1(a)~~**~~: the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;~~ | **~~Please select~~** |
| **~~GSPR 10.1(b):~~** ~~the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and,~~ | **~~Please select~~** |
| **~~GSPR 10.1(b):~~** ~~where relevant, absorption, distribution, metabolism and excretion (see Section~~ [~~6.2.7~~](#_Substances_or_combinations)~~)~~ | **~~Please select~~** |
| **~~GSPR 10.2:~~** ~~Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.~~ | **~~Please select~~** |

~~Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.~~

### Physical, chemical and microbiological characterisation (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Reviewer’s comment: Not applicable, the product under assessment is a medical device software.

Reference to documents assessed considering physical, chemical and microbiological characterisation (Document ID no or section of TD): Click or tap here to enter text.

For chemical characterisation also refer to biocompatibility, section 6.1.3.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case an additional surveillance activities was recommended, please copy them and the justifications thereof verbatim into section 10 of this report.

If the assessment module was not assessed by an expert, please delete the following section.

#delete-start

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The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusions drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. If no ASA is recommended, please delete the following sentence:

#delete-end

#unhide-start

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Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

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#unhide-end

Conclusion as applicable to this assessment module

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| --- | --- |
| **GSPR 10.1(a):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability. | **Please select** |
| **GSPR 10.1(c):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the compatibility between the different parts of a device which consists of more than one implantable part; | **Please select** |
| **GSPR 10.1(d):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the impact of processes on material properties; | **Please select** |
| **GSPR 10.1(e):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to, where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand; | **Please select** |
| **GSPR 10.1(f):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance; | **Please select** |
| **GSPR 10.1(g):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to surface properties; | **Please select** |
| **GSPR 10.1(h):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to the confirmation that the device meets any defined chemical and/or physical specifications | **Please select** |
| **GSPR 10.3:** Devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use; if the devices are intended to administer medicinal products they shall be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products and that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Electrical safety (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

*If no expert report is required, please verify the following:*

In the event of a single fault condition, appropriate measures shall be adopted to eliminate or reduce risks

Where patient safety may be affected, devices shall be equipped with a means of determining state of power supply and an appropriate warning/ indication for when power supply capacity becomes critical

Devices designed and manufactured to reduce the risks of creating electromagnetic interference as far as possible

Devices designed and manufactured to provide adequate level of intrinsic immunity to electromagnetic disturbance

Devices designed and manufactured to avoid the risk of accidental electric shocks to users

If the assessment module was not assessed by an expert, please complete the following section:

Reviewer’s comment: Medical device software is according to MDR an active medical device, however, electrical safety doesn’t apply.

Reference to documents assessed considering electrical safety (Document ID no/version or date or section of TD assessed): Click or tap here to enter text.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

If the assessment module was assessed by an expert, please complete the following section.

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text. , version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert is shown below: Please copy the GSPRs of the expert report verbatim in the evaluation table below.

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#delete-end

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#unhide-end

Conclusion as applicable to this assessment module

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| --- | --- |
| **GSPR 14.2(a):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features; | **Please select** |
| **GSPR 14.2(b):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; | **Please select** |
| **GSPR 14.2(c):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use; | **Please select** |
| **GSPR 14.2(f):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given; | **Please select** |
| **GSPR 14.2(g):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism. | **Please select** |
| **GSPR 14.3:** Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion. | **Please select** |
| **GSPR 18.1:** For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. | **Please select** |
| **GSPR 18.2:** Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical. | **Please select** |
| **GSPR 18.3:** Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure. | **Please select** |
| **GSPR 18.4:** Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | **Please select** |
| **GSPR 18.7:** Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer. | **Please select** |
| **GSPR 21.1:** Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to assure the safety of the patient and of the user. | **Please select** |
| **GSPR 21.2:** Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Electromagnetic compatibility / ionising and non-ionising radiation (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

|  |  |
| --- | --- |
| The device is an active device, but not a software. | NO |

Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the inherent risks must be included in the Risk Analysis and Clinical Evaluation. The design of the emissions control by the user must be evaluated regarding functional safety. The design of such devices shall ensure reproducibility and tolerance of relevant variable parameters.

Exposure to radiation (intended, unintended, stray or scattered) reduced as far as possible

Emission of (potentially) hazardous ionising and/or non-ionising radiation by the device can be controlled and/or adjusted and is fitted with visual displays and/or audible warnings

Operating instructions include information on the nature of the emitted radiation, means of protection and ways of avoiding misuse and of reducing risks at installation (warning symbols on labels and IFU)

Information to user specifying acceptance/ performance testing and acceptance criteria as well as maintenance procedure

Packaging/ shielding for transport (contamination control) as appropriate

Reference to documents assessed considering electromagnetic compatibility / ionising and non-ionising radiation (Document ID no or section of TD): Click or tap here to enter text.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

If the assessment module was assessed by an expert, please complete the following section.

#delete-start

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The expert concluded: *Please copy the conclusion of the expert report verbatim*: Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert is shown below: *Please copy the GSPRs of the expert report verbatim in the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

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Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

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**Conclusion as applicable to this assessment module**

|  |  |
| --- | --- |
| **GSPR 16.1(a):** Devices shall be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes. | **Please select** |
| **GSPR 16.1(b):** The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified | **Please select** |
| **GSPR 16.2(a):** Where devices are designed to emit hazardous, or potentially hazardous, levels of ionizing and/or non-ionizing radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent to the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance. | **Please select** |
| **GSPR 16.2(b):** Where devices are intended to emit hazardous, or potentially hazardous, levels of ionising and/or non-ionising radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions. | **Please select** |
| **GSPR 16.3:** Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible. Where possible and appropriate, methods shall be selected which reduce the exposure to radiation of patients, users and other persons who may be affected. | **Please select** |
| **GSPR 16.4(a):** Devices intended to emit ionising radiation shall be designed and manufactured taking into account the requirements of the Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. | **Please select** |
| **GSPR 16.4(b):** Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment. | **Please select** |
| **GSPR 16.4(c):** Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve an image and/or output quality that are appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user. | **Please select** |
| **GSPR 16.4(d):** Devices that emit ionising radiation and are intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation. | **Please select** |
| **GSPR 18.5:** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment. | **Please select** |
| **GSPR 18.6:** Devices shall be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### MR Safety - MR Conditional/Safe (MDR Annex II Section 6.1(b)) N/A

Reviewer’s comment: Software as a medical device, therefore EMC is not applicable.

For the MRI safety status of the device or system please refer to Section 1.1.12.

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted. This applies to the subsections as well.

If the assessment module was assessed by an expert and reportet in the expert report (ID: 231422), please refer to the expert report and delete until the the subheadline “Conclusion as applicable to this assessment module”.

#delete-start

Reference to documents assessed considering functional safety (document ID no or section of TD): Click or tap here to enter text.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

**MR conditional or MR safe device combinations:**

Please list devices and device combinations; or supply a different overview (e.g. table / matrix) of the system components that claim MR Conditional or MR Safe.

Provide additional information on device settings (MRI mode description is applicable to active medical implants).

**Risk management consideration of MR conditional or MR safe:**

Are hazards introduced through the MR Conditional and MR Safe considered in the risk management? Please provide a statement that all hazards connected to the device are considered within the risk management documentation. Type of information which might be applicable are:

* Heating considerations (radiofrequency and gradient)
* Force and torque acting on the device
* Damage/Malfunction of the device
* Performance of the device during and after MRI procedure.
* Other (e.g. vibration, artifact, …)

Please check furthermore the risk mitigation methods and the connection to the instructions for use.

MRI scanner conditions:

If multiple different device combinations are to be considered for the device / device systems include additional tables or consider other measures to allow unambiguous overview.

If certain elements of the table are not applicable the manufacturer shall ensure that there is no hazardous situation arising from this unconstrained type. Furthermore, ensure these elements are mentioned in the instructions for use or the MRI guideline and are in alignment with the tests conducted justifying MR conditional or MR safety.

If additional information is provided concerning the preparation of the patient undergoing the MRI procedure please provide an overview.

|  |  |  |
| --- | --- | --- |
| Type | Value |  |
| MRI Scanner Type | Horizontal, Open, Closed, Vertical Bore | |
| Radiofrequency System | Whole Body Coil, Elliptical Whole Body Coil, Circular Polarization, Elliptical Polarization | |
| Magnet Strength | 1.5 T | 3.0 T |
| Maximum Spatial Gradient field of B0 | XX T/m | XX T/m |
| Head SAR or B1+RMS | XX W/kg – or provide a B1RMS | XX W/kg – or provide a B1RMS |
| Whole Body SAR or B1+RMS | XX W/kg – or provide a B1RMS | XX W/kg – or provide a B1RMS |
| Gradient Slew Rate | XX T/m/s | XX T/m/s |
| Scan Time Limitation | If there are scan time limitations, please include relevant information here |  |
| Scan Zone Restrictions | If there are scan zone restrictions, please include relevant information here |  |
| Additional Restrictions |  |  |

MRI safety labelling:

*Please provide information on the compliance of the labelling according to ASTM-F2503 and other applicable standards (e.g. device specific, ISO 10974 Clause 18). To be checked:*

* *MR conditional / MR safe label according to ASTM-F2503 on the sales package label*
* *MR conditional / MR safe label according to ASTM-F2503 on the instructions for use*
* *MR conditional / MR safe label according to ASTM-F2503 on the implant card*

*Following sentence can be used:*

The labelling of MR conditional / MR safe is in compliance to ASTM-F2503 and is included in the salespackage labelling*, implant card and* instructions for use.

#delete-end

#unhide-start

This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and, if applicable, a gap analysis are included in [MED\_T\_09.61](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to MED\_T\_09.61 and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

#unhide-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 14.2(b):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences; | **Please select** |
| **GSPR 18.5:** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

#### MRI testing of implantable devices N/A

|  |  |
| --- | --- |
| Is the device an active implantable device? | Please select |

If yes, please delete the following table and refer to the expert report ID: 231422 (statement below).  
If no, please continue with the assessment in this document.

#delete-start

|  |  |
| --- | --- |
| The RF-heating hazard is considered by the manufacturer.  RF heating effects are applicable to the device if the device is conductive. SOTA of this intent is provided through ASTM-F2182. If simulations are used (other than worst-case selection) to provide evidence ISO 10974 clause 8 is considered SOTA.  Documented evidence:  List the documented evidence concerning to this hazard and ensure the test conditions fit to the information provided by the manufacturer (Magnet Field Strength, SAR or B1+RMS, Scan Time Duration, Scan Zone Restrictions) | **Please select** |
| Magnetic field induced force is considered by the manufacturer.  Magnetic field induced force is applicable to devices which are magnetic and magnetizable. SOTA of this intent is provided through ASTM-F2052.  Documented evidence:  List the documented evidence concerning to this hazard and ensure the test conditions fit to the information provided by the manufacturer (Magnet Strength, Maximum Spatial Gradient) | **Please select** |
| Magnetic field induced torque is considered by the manufacturer.  Magnetic field induced torque is applicable to devices which are magnetic and magnetizable. SOTA of this intent is provided through ASTM-F2213.  Documented evidence:  List the documented evidence concerning to this hazard and ensure the test conditions fit to the information provided by the manufacturer (Magnet Strength) | **Please select** |
| Additional hazards considered by the manufacturer.  Additional hazards can be based on large medical implants (e.g. gradient field induced heating and vibration). Furthermore, the device performance might be affected by the device undergoing an MRI procedure. SOTA of this intent are covered in device specific standards. Additionally, ISO 10974 test procedures can be leveraged.  Documented evidence:  *List the documented evidence concerning to this hazard and ensure the test conditions fit to the information provided by the manufacturer* | **Please select** |

The statement on fulfilment of GSPRs and conclusion related to MRI testing are provided in Section 6.1.7

#delete-end

If the assessment module was assessed by an expert within the expert report ID: 231422, please complete the following sections.

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert are shown under 6.1.7.

*Please copy the GSPRs of the expert report verbatim in the evaluation in the referenced in Conclusion as applicable to this assessment module.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

#### MRI testing of external (non-implantable) devices N/A

If “N/A” is selected above this section becomes irrelevant and shall be deleted. Before starting the assessment of the device or device system the location where the device is used (i.e. within the bore of the MRI system or within the MRI system scanner room) is essential to be defined by the manufacturer and shall be mentioned within the IFU.

#delete-start

|  |  |
| --- | --- |
| Magnetic field induced force is considered by the manufacturer.  Magnetic field induced force is applicable to devices which are magnetic and magnetizable. SOTA of this intent is provided through ASTM-F2052.  Documented evidence:  List the documented evidence concerning to this hazard and ensure the test conditions fit to the information provided by the manufacturer (Magnet Strength, Maximum Spatial Gradient) | **Please select** |

The statement on fulfilment of GSPRs and conclusion related to MRI testing are provided in Section 6.1.7

#delete-end

### Functional safety (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

|  |  |
| --- | --- |
| The device is an active device. | YES |

If Functional safety is applicable, please check relevant PPP and risk management file

#delete-start

If the assessment module was not assessed by an expert, please complete the following sections.

Reference to documents assessed considering functional safety (document ID no or section of TD): Click or tap here to enter text.

The following tests were performed by the manufacturer to show compliance with the manufacturer’s specifications and General Safety and Performance Requirements including evaluation of requirements based on the state of the art: Click or tap here to enter text.

#delete-end

If the assessment module was assessed by an expert, please complete the following sections.

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim in the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

#unhide-start

This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis, are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

#unhide-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 21.1:** Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.  Reviewer’s comment:  These functional safety aspects are not applicable to this software as a medical device and also excluded from PPP | **N/A** |
| **GSPR 21.2:** Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.  Reviewer’s comment:  These functional safety aspects are not applicable to this software as a medical device and also excluded from PPP | **N/A** |
| **GSPR 21.3:** The function of the controls and indicators shall be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information shall be understandable to the user and as appropriate, the patient. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Cyber Security (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

|  |  |
| --- | --- |
| The device incorporates cyber security elements. | Please select |

According to

MDCG 2019-16 Guidance on Cybersecurity for medical devices

EC 60601-1:2020 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-4-5 IT security

IEC 62304 Medical device software – Software life cycle processes

ISO 14971 Risk management

IEC 80001 Application of risk management for IT-networks incorporating medical devices

If the assessment module was not assessed by an expert, please complete the following sections.

Reference to documents assessed considering Cyber Security (Document ID no. or section of TD): Click or tap here to enter text.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

If the assessment module was assessed by an expert, please complete the following section.

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim in the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

#unhide-start

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Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

#unhide-end

Conclusion as applicable to this assessment module

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| --- | --- |
| **GSPR 17.2:** For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation. | **Please select** |
| **GSPR 17.4:** Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | **Please select** |
| **GSPR 18.8:** Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended. | **Please select** |
| **GSPR 23.4(a):** The instructions for use shall contain the particulars referred to in (a), (c), (e), (f), (k), (l), (n) and (r) of Section 23.2 *(see Section 2.22 of this report)* | **Please select** |
| **GSPR 23.4(b):** The instructions for use shall contain the device’s intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users as appropriate; | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Software verification and validation (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Description of the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer.

According to

MDCG 2020-1\_Guidance on Clinical Evaluation (MDR)\_Performance Evaluation (IVDR) of Medical Device Software

MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

IEC 62304:2015 - Medical device software – Software life cycle processes

IEC 82304-1:2016 - Health software – Part 1: General requirements for product safety

IEC 62366-1:2015 - Medical devices – Part 1: Application of usability engineering to medical devices

IEC 60601-1:2020 - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

|  |  |
| --- | --- |
| The device incorporates electronic programmable systems, including software, or the device per se constitutes software: | Please select |

If the assessment module was not assessed by an expert, please complete the following sections.

Reference to documents assessed considering Software Verification and Validation documents (Document ID no. or section of TD): Click or tap here to enter text.

Description of different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer: Click or tap here to enter text.

Description of the electronic programmable systems, software design and development process: Click or tap here to enter text.

Evidence of the validation of the software, as used in the finished device: Click or tap here to enter text.

Summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release: Click or tap here to enter text.

Proof of compliance with the manufacturer´s specifications and General Safety and Performance Requirements including evaluation of requirements based on the state of the art, was requested for the following key assumptions made as the basis for acceptance/verification. *Standards in accordance with PPP, if applicable or alternative methods.* The manufacturer provided sufficient and acceptable rationales: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications verbatim into Section 10 of this report.

#delete-end

If the assessment module was assessed by an expert, please complete the following section.

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim in the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

#unhide-start

This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and, if applicable, a gap analysis are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Therefore, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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Conclusion

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| --- | --- |
| **GSPR 14.2(d):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts; | **Please select** |
| **GSPR 17.1:** Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance. | **Please select** |
| **GSPR 17.2:** For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation. | **Please select** |
| **GSPR 17.3:** Software hat is intended to be used in combination with mobile computing platforms is designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise). | **Please select** |
| **GSPR 17.4:** Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Stability, including shelf life of the device (MDR Annex II Section 6.1(b))

#### Shelf life of the device (MDR Annex II Section 6.1(b))

Shelf life is to be assessed for the final device and, if applicable, for its sterile packaging system (refer to Section 6.1.12).

Verify qualification demonstrating that the device characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.

Stability and lifetime of implants in human beings must also be considered during the assessment process in the clinical evaluation.

Reviewer’s comment: product under assessment is a medical device software.

For the shelf life claimed refer to Section 1.1.12.

Reference to documents assessed considering shelf life and stability (Document ID no or section of TD): n/a

|  |  |
| --- | --- |
| Shelf life was proven by accelerated aging: | N/A |
| Shelf life was proven by real-time aging: | N/A |

The following conditions have been chosen for stability studies: n/a

Include a brief description of the main tests performed on the final device after the shelf life study has been performed.

Proof of compliance with the manufacturer´s specification and General Safety and Performance Requirements, including evaluation of requirements based on the state of the art, was requested for the following key assumptions made as the basis for acceptance/verification. *Standards in accordance with PPP, if applicable or alternative methods.* The manufacturer provided sufficient and acceptable rationales: n/a

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#unhide-start

This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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The shelf life of the final device is granted as claimed and matches the packaging shelf life (refer to Section 6.1.12).

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 6:** The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions | **N/A** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: n/a

#### Lifetime of the device (MDR Annex II Section 6.1(b))

Lifetime is the time duration a device has to achieve its intended purpose.

Stability and lifetime of implants in human beings must also be considered during the assessment process in the clinical evaluation. If the lifetime cannot be shown by PMCF data or clinical data so far, the verification can be done by

Data gained from legacy devices for x years

Risk based data received from substantiated justifications/ simulated use tests for x + y years

PMS data review

PMCF study plan includes lifetime for x+y years

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 7:** Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Packaging (MDR Annex II Section 6.1(b)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

For a brief description of the packaging, storage conditions and shelf life claimed refer to Section 1.1.12.

|  |  |
| --- | --- |
| The device is sterile. | NO |

If the device is not sterile and the assessment module was not assessed by an expert, please complete the following sections.

Reference to documents assessed considering transport and packaging validation as applicable to the non-sterile device (Document ID no or section of TD): Click or tap here to enter text.

Proof of compliance with the manufacturer´specifications and General Safety and Performance Requirements, including evaluation of requirements based on the state of the art, was requested for the following key assumptions made as the basis for acceptance/verification. The manufacturer provided sufficient and acceptable rationales: Click or tap here to enter text.

The packaging shelf life of the device is granted as: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. If no ASA is recommended, delete the following sentence:

#delete-end

If the device is sterile and the assessment module was assessed by an expert, please delete the following section.

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text..

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim in the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

#unhide-start

This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis, are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 6:** The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions | **Please select** |
| **GSPR 7:** Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.  dropping, stacking, vibration, storage/ handling temperature as specified by the manufacturer, humidity causing visible deterioration of packaging, markings, labels, or accompanying documents, indelible markings | **Please select** |
| **GSPR 11.1(c):** Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 11.1(d):** Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: prevent microbial contamination of the device or its content such as specimens or fluids  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 11.3:** Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 11.4:** Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 11.5:** Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 11.6**: Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 11.7:** Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.  Reviewer’s comment: product under assessment is a medical device software.  dropping, stacking, vibration, storage / handling temperature as specified by the manufacturer, humidity causing visible deterioration of packaging, markings, labels, or accompanying documents, indelible markings | **N/A** |
| **MDR Article 10.11:** Indelible marking on non-reusable pack. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Performance and safety (MDR Annex II Section 6.1(b))

The documentation shall contain the results of all the verification and validation testing and/ or studies undertaken and their critical analysis to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

The documentation shall contain 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 performance and safety. The former sections constructional and mechanical safety are included in this section.

For in-depth assessment of the general safety and performance requirements use PPP NAM AMP MDR General Requirements and all applicable device-/technology-specific PPPs.

For products without an intended medical purpose (MDR Art. 61 (9), CS (EU) 2022/2346 for Annex XVI devices).

Manufacturers shall substantiate in the technical documentation that devices achieve the intended performance as described in the information supplied with the devices.

Performance statements shall be phrased in terms that are consistent with the expectations of consumers. In order to substantiate that this is the case, the expectations of the target consumers shall be investigated.

Reference to documents assessed considering performance and safety (Document ID no or section of TD): Click or tap here to enter text.

#delete-start

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

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This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis, are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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Conclusion as applicable to this assessment module

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| **GSPR 9:** For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. | **Please select** |
| **GSPR 10.5:** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used | **Please select** |
| **GSPR 14.2(e):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks of accidental ingress of substances into the device. | **Please select** |
| **GSPR 14.2(f):** Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 14.4:** Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. | **Please select** |
| **GSPR 19.1(a):** Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 19.1(b):** Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 19.1(c):** Active implantable devices shall be designed and manufactured in such a way as to remove or minimize as far as possible: risks which may arise where maintenance and calibration are impossible, including:   * excessive increase of leakage currents, * ageing of the materials used, * excess heat generated by the device, * decreased accuracy of any measuring or control mechanism.   Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 19.2**: Active implantable devices shall be designed and manufactured in such a way as to ensure   * if applicable, the compatibility of the devices with the substances they are intended to administer, and * the reliability of the source of energy.   Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 19.3:** Active implantable devices and, if appropriate, their component parts shall be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 19.4:** Active implantable devices shall bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); it shall be possible to read this code, if necessary, without the need for a surgical operation  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 20.1:** Devices shall be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 20.2:** Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 20.3:** Devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 20.4:** Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, shall be designed and constructed in such a way as to minimise all possible risks.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 20.5:** Errors likely to be made when fitting or refitting certain parts which could be a source of risk shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.  The same information shall be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |
| **GSPR 20.6:** Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.  Reviewer’s comment: product under assessment is a medical device software. | **N/A** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Clinical data, Clinical Evaluation Report, PMCF plan, and PMCF evaluation report (MDR Articles 10.3, 61; Annex II Sections 6.1©, 6.1(d); Annex III; Annex XIV)

|  |  |
| --- | --- |
| The CEAR (Clinical Evaluation Assessment Report) covers all devices, and if applicable, variants and accessories and combined devices under assessment. | Please select |

Please note, that in case of class IIb active devices intended to administer and/or remove a medicinal product (rule 12), the CEAR must be completed for every single Basic UDI-DI; whereas the remaining parts of the TDAR can be sampled according to MDCG 2019-13 and Annex IX, section 5.1.

For products without an intended medical purpose (Annex XVI):

CS requirements must be considered

The requirement to demonstrate a clinical benefit shall be understood as a requirement to demonstrate the performance of the device (MDR Article 61 (9))

Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified (MDR Article 61 (9)))

This assessment module was reviewed by an authorised expert and is documented in the Clinical Evaluation Assessment Report (CEAR) report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: Please copy the conclusion of the expert report verbatim: Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities which are documented as specific milestones in [Clinical Evaluation Assessment Report (CEAR) (ID 2487)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2487), please copy them and the justifications thereof verbatim into Section 10 of this report.

Evaluation

|  |  |
| --- | --- |
| **GSPR 1:** Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. | **Please select** |
| **GSPR 8:** All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use. | **Please select** |
| **GSPR 9:** For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

#### Consultation of Clinical Evaluation (MDR Article 54)

|  |  |
| --- | --- |
| The device under assessment requires to follow the clinical evaluation consultation procedure in accordance with Article 54 | Please select |

Applicable only to class III implantable and class IIb active devices intended to administer and/or remove a medicinal product (rule 12) if such an assessment was conducted, please document the conclusion below in the table otherwise delete the table.

|  |  |
| --- | --- |
| MDR Article 54.2: The device does require a clinical evaluation consultation | Please select |

In case the device falls under one of the above categories and does not require a clinical evaluation consultation please justify why it does not require this consultation see [MDR](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=40648) Article 54.2 and MDCG 2019-3 for exceptions.

Rational that clinical evaluation consultation is not needed. Click or tap here to enter text.

If “no” is selected above (device does not require a clinical evaluation consultation) this section becomes irrelevant and shall be deleted. Please consider, that even if the class II or rule 12 IIb active device is excluded, cCE needs to submit notification to ZLG in accordance with [Consultation and Scrutiny for certain Class III and some Class IIb Medical Devices (ID 2853)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2853) until EUDAMED is fully functional.

#delete-start

|  |  |
| --- | --- |
| The expert panel concluded the clinical evaluation consultation with | the decision not to provide an opinion after 21 days  with an opinion after 60 days  with no opinion after 60 days |

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert panel opinion has been taken into consideration by the authorised expert, the concluding decision is documented in the referenced expert report.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The conclusion drawn by the expert is shown below: *Please copy the conclusion of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. If no ASA is recommended, delete the following sentence:

#delete-end

#### Scrutiny for certain class III and IIb devices (MDR Article 55, 54 (1))

Valid for devices mentioned in MDR Article 54 (1), addressed in section 6.1.14.1.

|  |  |
| --- | --- |
| A **scrutiny procedure** in accordance with MDR Article 55 with the competent authorities and, if applicable, with the commission will be initiated by TÜV SÜD Product Service GmbH after certification | Please select |

## Additional information required in specific cases (MDR Annex II Section 6.2)

### Substances considered to be a medicinal product (MDR Articles 1.6(d), 1.8) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Where a device incorporates, as an integral part, a substance which, if used separately, may be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, as referred to in the first subparagraph of Article 1(8), please provide a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

|  |  |  |  |
| --- | --- | --- | --- |
| |  |  | | --- | --- | | The device incorporates medicinal substance | NO | |  |

Brief description of medicinal substances: reference to Section 1.1.11.

#delete-start

A consultation was not deemed necessary, as Click or tap here to enter text.

#delete-end

#delete-start

The manufacturer provided evidence that the legacy device has not been significantly changed. A declaration Click or tap here to enter text. has thus been provided to the competent authority to shorten the consultation process.

#delete-end

#delete-start

MDR Annex IX.5.2(b): A consultation in accordance with Directive 2001/83/EC was performed.   
The consultation of the medicinal substance was conducted by the following competent authority: Click or tap here to enter text. under ID: Click or tap here to enter text.

Include the evaluation from the competent authority for medicinal products and the TÜV SÜD report

The competent authority documented their results in report no. Click or tap here to enter text., dated/version Click or tap here to enter text.. The results were considered by the expert.

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:* Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

Conclusion as applicable to this assessment module

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| **GSPR 12.1.** In the case of devices referred to in the first subparagraph of Article 1(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of point (2) of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as required by the applicable conformity assessment procedure under this Regulation. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Substances derived from human blood or human plasma (MDR Articles 1.6(d), 1.6(g), 1.8, 1.10) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), please provide a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device.

|  |  |
| --- | --- |
| The device incorporates medicinal substances derived from human blood or plasma derivatives. | NO |

Brief description of medicinal substances derived from human blood or human plasma: Reference to Section 1.1.11:

#delete-start

A consultation was not deemed necessary, as Click or tap here to enter text.

#delete-end

#delete-start

MDR Annex IX.5.2(a): A consultation in accordance with Directive 2001/83/EC was performed. The consultation of the medicinal substance was conducted by EMA ID: Click or tap here to enter text.

Include the evaluation from the EMA for human blood, plasma derivatives and the TÜV SÜD report

The competent authority documented their results in report no. Click or tap here to enter text.*.*, dated/version Click or tap here to enter text.. The results were considered by the expert.

#delete-end

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:*

Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

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This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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Conclusion as applicable to this assessment module

GSPR 13 Devices incorporating materials of biological origin

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| **GSPR 13.1(a):** For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC. | **Please select** |
| **GSPR 13.1(b):** For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. | **Please select** |
| **GSPR 13.1(c):** For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

Note: MDR Annex IX 6: Batch verification: Upon completing the manufacture of each batch, the manufacturer shall inform the Notified Body of the release of the batch of devices and send the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114 (2) of Directive 2001/83/EC, to the Notified Body.

### Tissues or cells of human origin (MDR Articles 1.6(d), 1.6(g), 1.8, 1.10) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Where a device is manufactured utilising tissues or cells of human origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6), and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device, and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), please provide a statement indicating this fact. In such a case, the documentation shall identify all materials of human origin used and provide detailed information concerning the conformity with Annex I Sections 13.1 or 13.2 as applicable.

|  |  |
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| The device incorporates medicinal substances derived from tissues or cells of human origin or their derivatives. | NO |

Brief description of tissue or cells of human origin or their derivatives: Reference to Section 1.1.11:

#delete-start

A consultation was not deemed necessary, as Click or tap here to enter text..

#delete-end

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MDR Annex IX 5.3.1: A consultation according to Directive 2004/23/EC was performed. The consultation of the tissues of human origin was conducted by the following competent authority: Click or tap here to enter text. under ID: Click or tap here to enter text.

Include the evaluation from the competent authority for tissue or cells of human origin and their derivatives and the TÜV SÜD expert report.

The competent authorities documented their results in report no. Click or tap here to enter text.*.*, dated/version Click or tap here to enter text.. The results have been considered by the expert.

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:*

Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

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This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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Conclusion as applicable to this assessment module

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| **GSPR 13.1 (a):** For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: (a) donation, procurement and testing of the tissues and cells shall be done in accordance with Directive 2004/23/EC. | **Please select** |
| **GSPR 13.1 (b):** For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: processing, preservation and any other handling of those tissues and cells or their derivatives shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. | **Please select** |
| **GSPR 13.1 (c):** For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable covered by this Regulation in accordance with point (g) of Article 1(6), the following shall apply: the traceability system for those devices shall be complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

Note: Before any changes are made with respect to non-viable human tissues or cells incorporated in a device and in particular related to its donation, testing or procurement, the manufacturer shall inform the Notified Body of the intended changes. The Notified Body shall consult the authority that was involved in the initial consultation, in order to confirm that the quality and safety of the tissues or cells of human origin or their derivatives incorporated in the device are maintained.

### Tissues or cells of animal origin (MDR Articles 1.6(f), 1.10) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Where a device is manufactured utilising tissues or cells of animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6), the documentation shall identify all materials of animal origin used and provide detailed information concerning the conformity with Annex I Sections 13.1 or 13.2 as applicable.

|  |  |
| --- | --- |
| The device utilises tissues or cells of animal origin or their derivatives | NO |
| The device utilises tissues or cells of animal origin referred to in Commission Regulation (EU) No 722/2012  This applies to animal tissues, and their derivatives originating from bovine, ovine and caprine species, deer, elk, mink and cats. | NO |

Brief description of tissue or cells of animal origin or their derivatives: Reference to Section 1.1.11.

#delete-start

If the medical device is manufactured utilising small amounts of tallow or tallow derivatives and where the tallow or tallow derivates are not major parts of the device, rule 18 (MDR) does not apply to classification. If the assessment module was not assessed by an expert, please complete the following section:

Reference to documents assessed considering materials of animal origin (Document ID no or section of TD): Click or tap here to enter text.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

#delete-end

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A consultation was not deemed necessary, as Click or tap here to enter text..

#delete-end

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The manufacturer provided evidence that the legacy device has not been significantly changed. A declaration Click or tap here to enter text. has thus been provided to the competent authority to shorten the consultation process.

#delete-end

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MDR Annex IX 5.3.2: A consultation according to Commission Regulation (EU) No. 722/2012 was performed. The competent authority documented their results in report no. Click or tap here to enter text. *,* dated/version Click or tap here to enter text.. The results have been considered by the expert.

#delete-end

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This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim.*

Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim in the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

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Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

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#unhide-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 13.2(a):** For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained by manufacturers. | **Please select** |
| **GSPR 13.2(b):** For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, shall be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device. | **Please select** |
| **GSPR 13.2(c):** For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following shall apply: in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Materials of biological origin N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

For devices manufactured utilising tissues of biological origin other than from animal or human origin and which are non-viable, the device and materials have to be evaluated with respect to:

processing, preservation, testing and handling of the substances

safety for patients, users, and where applicable, other persons

safety within the waste disposal chain

safety with regard to viruses and other transmissible agents

appropriate methods of sourcing

validated methods of elimination or inactivation in the course of the manufacturing process

consideration of possible exotoxins derived from the bacterial stem

risk analysis of the manufacturer concerning use of the biological origin material and the risks stated above.

The authorized expert (refer to MED\_W\_09.24, table 1) document their assessment in the Biological Safety Assessment Report.

|  |  |
| --- | --- |
| The device utilises non-viable biological materials other than materials of animal or human origin | NO |

Brief description of non-viable materials of biological origin other than animal or human origin: Reference to Section 1.1.11:

If the assessment module was assessed by an expert, please complete the following section:.

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim*

Click or tap here to enter text.

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In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 13.3**: For devices manufactured utilising non-viable biological substances other than those referred to in Sections 13.1 and 13.2, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Medical devices incorporating or consisting of nanomaterial (MDR Annex II Section 1.1(k)) N/A

If “N/A” is selected above this secition below becomes irrelevant and shall be collapsed or deleted.

|  |  |
| --- | --- |
| The device incorporates or consists of nanomaterial | NO |
| Nanoparticles come into contact with intact skin only | NO |

Brief description of nano materials: Reference to Section 1.1.11:

Reference to documents assessed considering nanomaterials (Document ID no or section of TD): Click or tap here to enter text.

|  |  |
| --- | --- |
| Does the risk classification of the device (MDR Annex II Section 1.1(f), Annex VIII) take into account rule 19? (Addendum to Section [1.1.6](#_Risk_class_of)) | Please select |
| Can the classification approach according to rule 19 be followed with regard to internal exposure *please provide the approach and reference supporting evidence:* Click or tap here to enter text. | Please select |
| Does the labelling include the nanomaterial symbol of ISO 15223-1: 2021? | Please select |
| Are the nanomaterials specified? ‘(Addendum to Section [1.1.10](#_General_description_of)) | Please select |

for characterisation of nanomaterials see below

List/specification of the nanomaterials:

|  |  |  |
| --- | --- | --- |
| Nanomaterial | Size | Use of nanomaterial (i.e. in which key functional element or other) |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| Does risk management for design and construction risks include the assessment of risks related to nanomaterials? (Addendum to Section 5) | Please select |

|  |  |  |
| --- | --- | --- |
| Identified risk | Mitigation measure | Acceptance |
|  |  |  |
|  |  |  |

|  |  |
| --- | --- |
| Does the biocompatibility assessment of the device (MDR Annex II Section 6.1(b)) address ISO/TR 10993-22 as applicable and was the potential impact of nanomaterials on conventional biocompatibility testing assessed by the manufacturer? (Addendum to Section [6.1.3](#_Biocompatibility_of_the)) | Please select |
| Physical, chemical and microbiological characterisation of the nanomaterials available (MDR Annex II Section 6.1(b)) (Addendum to Section [6.1.4](#_Physical,_chemical_and)) | Please select |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Nanomaterial | Property 1 [value] | Property 2 [value] | Property 3 [value] | Property 4 [value] | Property 5 [value] |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Characteristics as:

Agglomeration state:

Aggregation:

Composition (e.g., chemical composition and structure):

Particle size:

Size distribution:

Purity/impurity:

Shape:

Solubility (hydrophobicity,liposolubility, water solubility)

Stability:

Surface area:

Surface chemistry:

Surface charge:

Coating characteristics:

|  |  |
| --- | --- |
| Is the physical characterisation of the size of the nanomaterials performed using at least two methods, one being electron microscopy (MDR Annex II Section 6.1(b)) (Addendum to Section [6.1.4)](#_Physical,_chemical_and) | Please select |

|  |  |  |
| --- | --- | --- |
| Nanomaterial | Size determination Method 1 | Size determination Method 2 |
|  |  |  |
|  |  |  |

In case additional surveillance activities are recommended, please copy them and the justifications thereof verbatim into Section 10 of this report.

#unhide-start

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Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

#unhide-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 10.6:** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks linked to the size and the properties of particles which are or can be released into the patient's or user's body, unless they come into contact with intact skin only. Special attention shall be given to nanomaterials. | **Please select** |

### Substances or combinations of substances that are absorbed by or locally dispersed in the human body (MDR Annex II Section 6.2(c)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to:

absorption, distribution, metabolism and excretion;

possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;

local tolerance; and

toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device.

In the absence of such studies, a justification shall be provided.

|  |  |
| --- | --- |
| Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body | NO |
| MDR Annex IX 5.4 (a): The device is absorbable or intended to be locally dispersed in the body | NO |
| MDR Annex IX 5.4 (b): The device is absorbable or intended to be systemically dispersed in the body | NO |

Brief description of substances or combinations of substances that are absorbed: Reference to Section 1.1.11:

#delete-start

In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or only locally dispersed in the human body, a consultation is not needed.

A consultation was not deemed necessary, as Click or tap here to enter text.

Include the evaluation from the competent authority or justification for waiving a consultation.

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In the case of devices or their products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, a consultation is needed.

MDR Annex IX 5.4 (b), GSPR 12.1: A consultation of the substances that are systemically absorbed by the human body to achieve their intended purpose was performed in accordance Directive 2001/83/EC. The competent authority documented their results in report no. Click or tap here to enter text., dated/version Click or tap here to enter text.. The results have been considered by the expert.

#delete-end

#delete-start

This assessment module was reviewed by an authorised expert in accordance with Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions. The result of the evaluation is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:*

Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 12.2**: Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex I to Directive 2001/83/EC for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under this Regulation. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### CMR or endocrine-disrupting substances (MDR Annex II Section 6.2(d)); hazardous substances, REACH, biocidal products N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Devices, or those parts thereof or those materials used therein that:

- are invasive and come into direct contact with the human body, or

- (re)administer medicines, body liquids or other substances, including gases, to/from the body, or

- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

containing:

- substances which are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, or

- substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health, and which are identified either in Regulation (EC) No 1907/2006 (REACH) or in Regulation (EU) No 528/2012

shall be identified and quantified in % weight by weight (w/w).

If the concentration is above 0.1% w/w a justification for the presence of these substances has to be evaluated.   
Justification shall be based on:

- Analysis and estimation of potential patient or user exposure to the substance;

- Analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer reviewed studies, scientific opinions from relevant Scientific Committees and analysis of the availability of such alternatives;

- Argumentation as to why possible substance and/or material substitutes or design changes, if available, are inappropriate for maintaining the functionality, performance and benefit-risk ratios of the product; including consideration of whether the intended use of such devices includes treatment of children or treatment of pregnant or nursing women or treatment of other patient groups considered particularly vulnerable to such substances and/ or materials;

- Where applicable and available, the latest relevant Scientific Committee guidelines

In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I and the justification referred to in Section 10.4.2 of that Annex.

Substances which are carcinogenic, mutagenic or toxic to reproduction (labelling according to Regulation (EC) No. 1272/2008 applies)

Please verify that the manufacturer justifies that CMR and/or endocrine substances are applicable, e.g., in the GSPR list and follow [MDR / IVDR Technical Documentation Assessment (ID 40648)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=40648) Section 5.7.2.8. In case the device contains such substances > 0.1% w/w, as e.g., cobalt (included in CoCr alloys or as an impurity in stainless steel), phthalate DEHP (used as plasticiser in PVC), bisphenol A (BPA), the following section is applicable.

|  |  |
| --- | --- |
| The device contains CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I with a concentration > 0.1% w/w | NO |

If “yes” please add relevant information, e.g. a justification for substances over 0.1% weight by weight

Reference to documents assessed considering CMR or ED substances documents (Document ID no or section of TD): Click or tap here to enter text.

Brief description of substances which are carcinogenic, mutagenic or toxic to reproduction (CMR) or which have endocrine-disrupting properties or other hazardous substances: Reference to Section 1.1.11:

Please list concentration per substance: Click or tap here to enter text. %w/w

The Material Safety Data Sheet according to Regulation (EC) No. 1907/2006 is made available (alternative: relevant information made available in instructions for use).

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

If the assessment module was not assessed by an expert, please delete the following section.

#delete-start

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Click or tap here to enter text.

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#unhide-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 10.4.1**: Design and manufacture of devices  Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. Devices, or those parts thereof or those materials used therein that:  are invasive and come into direct contact with the human body,  (re)administer medicines, body liquids or other substances, including  gases, to/from the body, or  transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body,  shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:  Note: Devices that come only in contact with intact skin are excluded from the above groups, therefore the below mentioned GSPRs are not applicable. | **Please select** |
| **(a)** substances which are carcinogenic, mutagenic or toxic to reproduction (‘CMR’), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council(1), or | **Please select** |
| **(b)** substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council(2) or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council (3), in accordance with the criteria that are relevant to human health amongst the criteria established therein. | **Please select** |
| **GSPR 10.4.2(a):** Justification regarding the presence of CMR and/or endocrine-disrupting substances  The justification for the presence of such substances shall be based upon: an analysis and estimation of potential patient or user exposure to the substance. | **Please select** |
| **GSPR 10.4.2(b):** Justification regarding the presence of CMR and/or endocrine-disrupting substances  The justification for the presence of such substances shall be based upon: an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives. | **Please select** |
| **GSPR 10.4.2(c):** Justification regarding the presence of CMR and/or endocrine-disrupting substances  The justification for the presence of such substances shall be based upon: argumentation as to why possible substance and/or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials; and | **Please select** |
| **GSPR 10.4.2(d):** Justification regarding the presence of CMR and/or endocrine-disrupting substances  The justification for the presence of such substances shall be based upon: where applicable and available, the latest relevant scientific committee guidelines in accordance with Sections 10.4.3. and 10.4.4. | **Please select** |
| **GSPR 10.4.3:** Guidelines on phthalates  For the purposes of Section 10.4., the Commission shall, as soon as possible and by 26 May 2018, provide the relevant scientific committee with a mandate to prepare guidelines that shall be ready before 26 May 2020. The mandate for the committee shall encompass at least a benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in points (a) and (b) of Section 10.4.1. The benefit-risk assessment shall take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments. When deemed appropriate on the basis of the latest scientific evidence, but at least every five years, the guidelines shall be updated. | **Please select** |
| **GSPR 10.4.4**: Guidelines on other CMR and endocrine-disrupting substances  Subsequently, the Commission shall mandate the relevant scientific committee to prepare guidelines as referred to in Section 10.4.3. also for other substances referred to in points (a) and (b) of Section 10.4.1., where appropriate. | **Please select** |
| **GSPR 10.4.5**: Labelling  Where devices, parts thereof or materials used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0.1 % weight by weight (w/w), the presence of those substances shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. If the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials, information on residual risks for those patient groups and, if applicable, on appropriate precautionary measures shall be given in the instructions for use. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Sterile devices (MDR Annex II Section 6.2(e)) N/A

If the device is not provided in a sterile condition or intended to be sterilised prior to use”N/A” can be selected. If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

In the case a sterile device is placed on the market , a description of the environmental conditions for the relevant manufacturing steps shall be available. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility shall be available. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues.

|  |  |
| --- | --- |
| The device is delivered in sterile condition | N/A |
| The device is intended to be sterilised | N/A |

Brief description of sterilisation method: Click or tap here to enter text.

Brief description of environmental conditions used for the relevant manufacturing steps, please refer to Section 3.2 and/or 6.2.9.

#delete-start

If the assessment module was not assessed by an expert, please delete the following section.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

#delete-end

If the assessment module was assessed by an expert, complete the following section.

#delete-start

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The expert concluded: *Please copy the conclusion of the expert report verbatim:*

Click or tap here to enter text.

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In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

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#unhide-start

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Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

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Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 10.1(d):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: the impact of processes on material properties. | **Please select** |
| **GSPR 10.4.1:** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. | **Please select** |
| **GSPR 11.4:** Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user. | **Please select** |
| **GSPR 11.5:** Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods. | **Please select** |
| **GSPR 11.8:** The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Infection risk and reusable device(s) or devices with defined microbiological condition (MDR Annex II Section 6.2(e)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

‘Reprocessing, reusable’ means a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device; Note: we do not certify single use devices that are reprocessed.

In the case of devices placed on the market in a defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps shall be available. Devices delivered with defined microbial conditions underwent e.g. a cleaning and/or disinfection step.

|  |  |
| --- | --- |
| The device is intended to be reused | NO |
| The device is intended to be (re-)sterilised by the user | NO |
| The device is delivered with defined microbiological conditions | NO |
| The device is intended to be set in a defined microbiological condition | NO |

Brief description of infection risk and reusable device: Click or tap here to enter text..

Include information on method

Brief description of the microbiological condition, cleaning/disinfection step: Click or tap here to enter text.

Brief description of environmental conditions used for the relevant manufacturing steps, please refer to Sections 3.2 and/or 6.2.9.

Reference to documents assessed considering infection risk and reusable devices (Document ID no or section of TD): Click or tap here to enter text.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

#delete-end

#delete-start

This assessment module was reviewed by an authorised expert and is documented in report no. Click or tap here to enter text., version Click or tap here to enter text.

The expert concluded: *Please copy the conclusion of the expert report verbatim:*

Click or tap here to enter text.

The statement on fulfilment of GSPRs and the conclusion drawn by the expert are shown below: *Please copy the GSPRs of the expert report verbatim into the evaluation table below.*

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

#unhide-start

This expert report was created for an assessment under the EC Directives. An authorised expert verified that the report takes into account the generally acknowledged state of the art as set forth in MDR Annex I. The evaluation of the assessment results under the EC Directives, a rationale for consideration of assessment results and if applicable, a gap analysis are included in [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) or the amended expert report. Given this, the expert report and conclusion on compliance can be considered for this assessment module.

Reference to expert report in accordance with EC Directive: Click or tap here to enter text.

Reference to [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777) and/or amended expert report: Click or tap here to enter text., version Click or tap here to enter text..

#unhide-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 10.1(d):** Devices shall be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Chapter I are fulfilled. Particular attention shall be paid to: Particular attention shall be paid to: the impact of processes on material properties; | **Please select** |
| **GSPR 11.1(a):** Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries. | **Please select** |
| **GSPR 11.1(b):** Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: allow easy and safe handling. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

If the device is not intended to be reused, all following can be deleted

#delete-start

|  |  |
| --- | --- |
| **GSPR 11.2:** Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation. | **Please select** |
| **GSPR 11.3**: Devices labelled as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer. | **Please select** |
| **GSPR 11.6:** Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities. | **Please select** |
| **MDR Annex VI – PART C, 6.2:** Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses. The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

#delete-end

### Devices with a diagnostic or measuring function (MDR Annex II Section 6.2(f)) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.

Taking account of the intended purpose the device provides sufficient accuracy, precision, and stability, within appropriate limits of accuracy for their intended purpose.

|  |  |
| --- | --- |
| The device has a diagnostic function | Please select |
| The device has a measuring function | Please select |

Brief description of diagnostic and/or measuring function: Reference to Section 1.1.10:

If the assessment module was not assessed by an expert, please complete the following sections.

#delete-start

Reference to documents assessed considering measuring function (document ID no or section of TD): Click or tap here to enter text.

Reference to documents assessed considering diagnostic function (document ID no or section of TD): Click or tap here to enter text.

Description given on methods used to ensure accuracy as given in the specifications:

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. If no ASA is recommended, delete the following sentence:

#delete-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| **GSPR 14.4:** Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. | **Please select** |
| **GSPR 14.6:** Any measurement, monitoring or display scale shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used. | **Please select** |
| **GSPR 15.1:** Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer. | **Please select** |
| **GSPR 15.2:** The measurements made by the devices with a measuring function shall be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC | **Please select** |
| **GSPR 23.4 (h):** The instructions for use shall contain all of the following particulars: specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it. | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

### Devices with connection to other device(s) (MDR Annex II Section 6.2(g) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer.

|  |  |
| --- | --- |
| The device is to be connected to other device(s) in order to operate as intended | Please select |

Brief description of connection to other devices/ equipment: Reference to Section 1.1.9:

If the assessment module was not assessed by an expert, please complete the following sections.

#delete-start

Reference to documents assessed considering connection to other devices (Document ID no or section of TD): Click or tap here to enter text.

Regarding performance and clinical evaluation as well as conclusions please see respective section of this report and/ or CEAR.

Compliance with the manufacturer’s specifications, the General Safety and Performance Requirements, and state-of-the-art requirements was verified against the applicable standards, PPP and/or the submitted customer documents. The results were acceptable and/or acceptable taking into account the following justifications: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report.

#delete-end

Conclusion as applicable to this assessment module

|  |  |
| --- | --- |
| Combinations of the device with other medical devices are addressed and tested by the manufacturer | **Please select** |
| **GSPR 14.1:** If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, shall be designed and constructed in such a way as to minimise all possible risks, such as misconnection. | **Please select** |
| **GSPR 14.5:** Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe. | **Please select** |
| Active devices and devices connected to them: |  |
| **GSPR 18.1:** For non-implantable active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks. | **Please select** |
| **GSPR 18.2:** Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical. | **Please select** |
| **GSPR 18.3:** Devices where the safety of the patient depends on an external power supply shall include an alarm system to signal any power failure. | **Please select** |
| **GSPR 18.4:** Devices intended to monitor one or more clinical parameters of a patient shall be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health. | **Please select** |
| **GSPR 18.5:** Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment. | **Please select** |
| **GSPR 18.7:** Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer. | **Please select** |
| **GSPR 18.8:** Devices shall be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended. | **Please select** |
| The combination of devices is described in the IfU | **Please select** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

# Summary of safety and clinical performance (SSCP) (MDR Article 32) N/A

If the device is no implantable device or class III device, an SSCP is not applicable. If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

|  |  |
| --- | --- |
| The device is an implantable device or class III device | NO |

Validate the SSCP in accordance with [Assessment of SSCP / SSP and PSUR for Medical Devices and IVD Products (ID 23949)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=23949).

In the case of products without an intended medical purpose (Annex XVI,) CS requirements shall be considered

Reference to documents assessed is considered in the SSCP Validation Statement:

The manufacturer´s Summary of Safety and Clinical Performance has been validated by an authorised expert in *(include language validated)* Click or tap here to enter text. and is documented in validation statement SSCP VS no. Click or tap here to enter text., version Click or tap here to enter text. *and will be uploaded to EUDAMED as soon as functional.*

The expert concluded: *Please copy the conclusion of the expert report 1:1* Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. :

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| MDR Article 32.1: IFU or labelling includes information of where the SSCP is available | Please select |
| MDR Article 32.2(a) – (h): The requirements of the MDR are fulfilled | Please select |

Note: Ensuring a timely submission of all SSCP updates and all SSCP translations to the notified body (MDCG 2019-9) falls under the manufacturer’s responsibility.

# Post-Market Surveillance

## Periodic Safety Update Report (PSUR) (MDR Articles 84, 85, 86; MDR Annex III) N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

Note: Ensuring a timely submission of the PSUR and informing the notified body that a PSUR has been uploaded to the electronic system EUDAMED (MDCG 2019-9, MDCG 2022-21) falls under the manufacturer’s responsibiity. As long as EUDAMED is not fully functional, the PSURs for all implantable and class III devices have to be submitted to TÜV SÜD in accordance with MDR Article 86.

This process starts after the initial MDR certification following the minimum reporting timelines as specified in MDR (annual for class III devices and class IIb implants/ biennial for class IIa implants).

The Periodic Safety Update Report (PSUR) was reviewed by an authorised expert and the results documented in the PSUR Evaluation Report PSURER no. Click or tap here to enter text. ,version Click or tap here to enter text..

The expert concluded: *Please copy the conclusion of the expert report 1:1:* Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report

# Additional regulations, procedures, directives, commission decisions

## Environmental protection, safety of disposal

Manufacturers shall identify and test procedures and measures for safely disposing of their devices after use. These procedures shall be described in the instructions for use.

Reviewer’s comment: product under assessment is a medical device software.

Reference to documents assessed considering Environmental protection, safety of disposal (Document ID no or section of TD): n/a

|  |  |
| --- | --- |
| Separate disposal required e.g. in accordance with 2012/19/EC on separate disposal of electronic waste (WEEE)) | N/A |

The following key assumptions made as the basis for acceptance/ verification to show compliance with the manufacturer´s specification and General Safety and Performance Requirements including evaluation of requirements based on the state of the art were challenged and the manufacturer provided sufficient and acceptable rationales: n/a

Procedures for safe disposal and environmental protection are described in the current version of the IFU, refer to section 2.2.

Conclusion as applicable for this assessment module

|  |  |
| --- | --- |
| **GSPR 14.7:** Devices shall be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person. To that end, manufacturers shall identify and  test procedures and measures as a result of which their devices can be safely disposed after use. Such procedures shall be described in the instructions for use. | **N/A** |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: n/a

## Other regulatory requirements N/A

If “N/A” is selected above this section below becomes irrelevant and shall be collapsed or deleted.

|  |  |
| --- | --- |
| The product falls under the regulation of regulatory requirements other than those referenced above in this document. | Please select |

List other applicable regulatory requirements: Click or tap here to enter text.

Other applicable specific procedures, supplementary directives, regulations, and commission decisions e.g:. MDR Article 1.12: Regulation (EU) 2023/1230 on Machinery,  
Radio Equipment Directive  2014/53/EU (RED)(does the device have wireless communication capability?),  
EU Regulation 2016/425 on personal protective equipment (PPE).    
Add information on the regulatory requirement and include documented evidence for compliance:

Reference to documents assessed considering other regulatory requirements: Click or tap here to enter text.

The following key assumptions made as the basis for acceptance/ verification were challenged to show compliance with the manufacturer´s specification and General Safety and Performance Requirements including evaluation of requirements based on the state of the art. *Standards in accordance with PPP, if applicable or alternative methods* The manufacturer provided sufficient and acceptable rationales: Click or tap here to enter text.

In case the expert has recommended additional surveillance activities, please copy them and the justifications thereof verbatim into Section 10 of this report. If no ASA is recommended, please delete the following sentence:

**Conclusion as applicable for this assessment module**

|  |  |
| --- | --- |
| The manufacturer considered the requirements of the regulation(s) listed above at the start of this section. | Please select |

# Additional Surveillance Activities (ASA) (MDR Annex VII Sections 4.6, 4.8, 4.10)

In case the applicable GSPRs are fulfilled, and additional tasks need to be followed up, include the requirements applicable to additional audits or actions from this assessment which need to be followed up. Document a justification for the additional surveillance activity. Indicate the date by which the follow-up needs to be fulfilled and whether the remark or follow-up has any influence on the recommendation for certification

If no such activity is required, the subsections which are not applicable can be deleted.

## Special audit of the QM system N/A

The following items require a special audit to expand the scope of the QM system:

List items, processes, elements which have to be addressed in the audit, please inform the CARE.

|  |  |
| --- | --- |
| Extra Audit Scope | To be audited by |
| Requirement: Click or tap here to enter text.  Justification: Click or tap here to enter text. | QMS/ TA/ PS/ Expert |

## Items for next regular audit N/A

These items have to be included in CBW by the PH, please inform the responsible Auditor and CARE.

The following items require action during the next audit:

|  |  |
| --- | --- |
| Item Description | To be audited by |
| Requirement: Click or tap here to enter text.  Justification: Click or tap here to enter text. | QMS/ TA/ PS/ Expert |

## Follow-up project N/A

Follow up items must be considered. Response and additional information are required by the manufacturer and has to be submitted as follow-up project. The follow up needs to be provided to TÜV SÜD to the date(s) defined below.

(These items have to be included as a follow up project in the respective Project Database (e.g. PSE) by the PH or corresponding PC)

Assigned Project Number for follow-up: Click or tap here to enter text.

|  |  |
| --- | --- |
| Follow-Up Description | Due Date |
| Requirement: Click or tap here to enter text.  Justification: Click or tap here to enter text. | YYYY-MM-DD |

## Recommended conditions on certification N/A

Use “Conditions” only in cases in which a limitation or condition must be stated **on the certificate** (e.g. additional contraindication, device distribution limited to study centres of PMCF study, or if, within the certification, the suspension of certificate has to be announced, certificate validity limitation, etc.). Refer to [Discontinuation of Certification, Certificate Maintenance under Condition, Withdrawal of refused Applications (ID 2559)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2559).

The final decision on a condition is made by the STC.

The following items shall be stated on the certificate:

|  |  |
| --- | --- |
| Condition | Delivered by |
| Condition: Click or tap here to enter text.  Justification: Click or tap here to enter text. | QMS/ TA/ PS/ Expert |

# Final Conclusion (MDR Annex VII Section 4.6)

**Select** the conclusion statement according to the path of conformity assessment and device classification. **Delete** statements which do not apply.

|  |  |
| --- | --- |
| **GSPR 1**: Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. | Please select |
| The device(s) under the BASIC UDI-DI as specified on p. 1 conform(s) to the relevant general safety and performance requirements as defined in MDR  Annex I;CS, MDCG and product specific standards, are fulfilled, where applicable | Please select |
| Annex VII, 4.5.3: Further tests or other evidence were required for the assessment of conformity: The following physical or laboratory tests were performed, or the manufacturer was requested to carry out such tests: Click or tap here to enter text..  Justification: Click or tap here to enter text. | Please select |
| (Continued) certification is recommended | Please select |
| Upload of the SSCP (see Section 7) to EUDAMED is recommended | NO |
| Upload of the relevant data for Scrutiny to EUDAMED is recommended (see Section 6.1.14.2). | Please select |

Provide justification/comments to conclusion, recommended ASAs or non-applicable GSPRs: Click or tap here to enter text.

In case the project exceeded 24 months from assessment of the 1st assessment module, please refer to [MDR / IVDR Technical Documentation Assessment Procedure (ID 59330)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=59330) to perform a gap analysis before completing the TDAR and submitting the file to Medici. Please unhide the following section:

#unhide-start

The project´s time limit of 24 months has been exceeded due to Click or tap here to enter text.,(please include reason for delay). A state-of-the-art gap analysis has been performed with the following result

An additional gap analysis as stated in the respective section of this TDAR/ [State-of-the-art Assessment for EU Regulations (ID 96777)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=96777). Click or tap here to enter text. / expert report Click or tap here to enter text. (please include the reference of the document and delete any that do not apply),

An additional surveillance activity in Section 10,

No additional gap assessment.

#unhide-end

|  |  |  |
| --- | --- | --- |
| TÜV SÜD Product Service GmbH Medical and Health Services |  | TÜV SÜD Product Service GmbH Medical and Health Services |
| {Department}  {Name}  Final Reviewer |  | {Department}  {Name}  Product Reviewer |
| The final reviewer (LTR-TD or STC):  performs the final review in accordance with [Certification Decision and Maintenance of Certification (ID 2552)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2552) and  provides the second signature of the TDAR |  | The Authorised Product Reviewer can only sign alone if all assessment modules are backed by separate reports signed by authorised PR´s /Experts/ CLRs.  Unless this condition is fulfilled, the TDAR must also be signed by the PR/expert |
| The following only applies in case of supervision. If the assessment is done by an authorised expert, please delete the following lines. | | |
|  |  |  |
|  |  | {Department}  {Name}  Supervised Reviewer |

We have read, understood and accepted the [Independence, Impartiality, Conflict of Interest and Confidentiality Requirements (ID 2576)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=2576) procedure. To the best of our knowledge we hereby declare that we are independent, impartial and objective in respect of this project and have no conflict of interest.

# Version History

Refer to [MHS Records Management (ID 74603)](https://roxtra.tuev-sued.com/Roxtra/doc/showfile.aspx?FileID=74603) concerning completing and modifying a record.

Please provide a detailed description of the changes as the tracking function of MS Word will not be visible in the approved record sent to the manufacturer. Include a short rationale for the change

| **No.** | **Date**  (yyyy-mm-dd) | **Name** | **Description of change** |
| --- | --- | --- | --- |
| 1 |  | %OFFICER\_IN\_CHARGE | Completion of record |
| 2 |  |  |  |
| 3 |  |  |  |