QUESTIONNAIRE ON THE ORGANIZATION, DEVICES AND CONFORMITY ASSESSMENT PROCEDURE WITH REGARD TO REGULATION (EU) 2017/745* ON MEDICAL DEVICES

* Regulation (EU) 2017/745 on medical devices (MDR) with all valid amendments and supplements

1. GENERAL INFORMATION ABOUT THE MANUFACTURER AND / OR EU AUTHORIZED REPRESENTATIVE / DISTRIBUTOR /IMPORTER

a) MANUFACTURER / DISTRIBUTOR / IMPORTER

Name:

_____

(A legally registered abbreviated name of the legal entity.)

_____

(Street, City, Postcode, Country)

Single registration number (SRN):

Director (Name and surname):_____

Email irector:_____

Contact person (Name and surname):_____

Phone:_____ Fax: _____ TAX Number:_____

Organization Email: _____ _____Web sites: _____

Statistical Classification of Economic Activities (NACE Rev. 2). (Select the code from document Statistical classification of economic activities in the European Community)* Please state the code(s) and the name(s) of the activity(ies).	

*https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF

b) EU AUTHORIZED REPRESENTATIVE

Name:

_____

(A legally registered abbreviated name of the legal entity.)

_____

(Street, City, Postcode, Country)

Single registration number (SRN):

Director (Name and surname):_____

Email director:_____

Contact person (Name and surname):_____

Phone:_____ Fax: _____ TAX Number:_____

Organization Email: _____Web sites: _____

2. INFORMATION ABOUT THE SITES, MANUFACTURING SITES, SUBCONTRACTORS, CRITICAL SUPPLIERS AND AFFILIATED COMPANIES

2.1. Organization's legal address / affiliated companies / other sites and processes

Organization's legal address and processes performed at legal address		
Name and address	Processes, performed on the site	Number of employees on this site

Affiliated companies*/Companies that are part of the same manufacturer group

**Examples: subsidiary company/daughter company, branch offices, related companies, manufacturing site, sales office, warehouse, design and development, packing/assembling*

Affiliated companies: ☐ yes* ☐ no

**state the affiliated companies:*

ID	Name and address	Processes, performed by the organization	Part of the same Quality management system	Number of employees on this site
1			☐ yes ☐ no	
2			☐ yes ☐ no	
3			☐ yes ☐ no	

Other sites:

Subcontractors* / Critical suppliers:**

** subcontracted processes and further subcontracted processes*

Examples of activities performed by the subcontractor: design and development, production, packing/assembling in the case of systems and procedure packs, sterilization process, etc.

***Critical supplier is a supplier delivering materials, components or services that may influence the safety and performance of the device (NBOG BPG 2010-1)*

ID	Name and address	Processes, performed by the organization
1		
2		
3		

2.2. Connection with founders of SIQ

Are you connected in any way (e.g. subsidiary company, subcontractor, distributor, manufacturer, importer...) with the following organizations that are the founders of SIQ, or their affiliated companies?

Gorenje d.d. ☐ yes ☐ no
Iskra d.d. ☐ yes ☐ no
Zavarovalnica Triglav ☐ yes ☐ no

If you marked "**yes**", please indicate the type of connection (e.g. subsidiary, subcontractor, distributor, manufacturer, importer...):	

Please enclose any available information material on the legal entity (company profile, annual report, sales catalogue, and the like).

3. QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES – ISO 13485

(fill out only in case of ISO 13485 certification procedure)

a) ACTIVITIES INCLUDED IN CERTIFICATION SCOPE

Please state the activities and devices/services that are covered by the management system and will be subject to certification.	
Please state any other activities and devices/services that are excluded from certification.	

b) AUDITING

Data on a management system(s) certified by SIQ or any other certification body(ies). Standard _____ Cert. body _____ Year of certification _____
Desired date of a certification procedure: _____

Please enclose any existing certificates.

c) CERTIFICATION SCOPE

☐ Common scope for the entire legal entity or ☐ Each organizational unit its own scope

d) PERSONNEL INVOLVED IN THE ESTABLISHMENT OF THE MANAGEMENT SYSTEM

Do you have or intend to have an external consultant?	YES ☐ NO☐

4. DEVICES TO BE APPROVED

(relevant in relation of issuing EU certificate)

ID	Device group / Device Name	Note*	Classification (according to Annex VIII of the regulation 2017/745 on medical devices)			
			class	rule	MD code	EMDN code
1						
2						
3						

** animal tissue, medicinal products, human blood/plasma derivates, nanoparticles used*

Description and intended use of medical device

ID	Description of medical device
1	
2	
3	
ID	Indication and intended use of medical device
1	
2	
3	
ID	The rationale for the qualification of the product as a medical device (Clause 7 Additional information for customer):
1	
2	
3	
Additional information for non-active non-implantable devices composed of substances	

(Please state the composition of the device indicating (main) active substances and auxiliary ingredients) **(Please describe the mechanism of action of a medical device)**

Please enclose Instructions for use.

Has your device been already placed on the EU market?	YES ☐ NO ☐

Technical documentation and clinical evaluation

List/Number of technical files
List/Number of clinical evaluations
Documentation language: ☐ Slovenian ☐ English ☐ Croatian

Devices with special characteristics:

Devices in sterile condition, or are sterilized by the user as recommended by the manufacturer Used method / process of sterilization (if relevant):
Aseptic processing: ☐ yes ☐ no
Steam: ☐ yes ☐ no
EtO: ☐yes ☐ no
Radiation: ☐ yes ☐ no
Other (please state)
Reusable surgical instruments: ☐ yes ☐ no
Devices incorporating software / utilising software / controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices: ☐ yes ☐ no
Devices incorporating medicinal substances: ☐ yes ☐ no
Devices manufactured utilising tissues or cells of human origin, or their derivatives: ☐ yes ☐ no Devices manufactured utilising tissues or cells of animal origin, or their derivatives: ☐ yes ☐ no
Devices which are also machinery as defined in 2(2)(a) Directive 2006/42/EC: ☐ yes ☐ no
Devices incorporating or consisting of nanomaterial: ☐ yes ☐ no
Devices utilising biologically active coatings and / or materials: ☐ yes ☐no Devices, being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body: ☐ yes ☐ no
Devices with a measuring function: ☐ yes ☐ no
Devices in systems or procedure packs : ☐ yes ☐ no

Products without an intended medical purpose listed in Annex XVI to MDR:	☐ yes	☐ no
Class III custom-made implantable devices :	☐ yes	☐ no
Devices that come into contact with user and/or patient:		
That come into contact with intact skin or mucous membrane:	☐ yes	☐ no
That come into contact injured skin or mucous membrane:	☐ yes	☐ no
Invasive, that come into contact with body orifice:	☐ yes	☐ no
Surgically invasive device:	☐ yes	☐ no

5. ASSESSMENT ROUTE APPLIED FOR
(relevant in relation of issuing EU certificate)

Device classes	**Assessment route applied for** (relevant Annex or Annexes)**	
Class Is device(s)		Note: Class I devices (excl. Sterile, devices with measuring function, reusable medical devices) do not require Notified Body intervention
Class Im device (s)		
Class Ir device (s)		
Class IIa device (s)		
Class IIb device (s)		
Class III device (s)		

***Annex IX (Conformity assessment based on a quality management system and on assessment of technical documentation)*
Annex X (Conformity assessment based on type-examination)
Annex XI part A (Conformity assessment based on production quality assurance)
Annex XI part B (Conformity assessment based on product verification)
Article 16 (Quality management system for distributors or importers, carrying out activities referred to in points (a) and (b) of paragraph 2)

6. GENERAL QUESTIONS AND REQUIREMENTS WITH RESPECT TO ANNEX XI part B of REGULATION 2017/745 MDR (indicate in case of assessment route according to Annex XI part B)

Requested verification method:	
LOT/batch or serial number identification of devices:	
Batch identification:	
Batch size:	
Production testing according to which standard(s):	

7. ADDITIONAL INFORMATION FOR CUSTOMER

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

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

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

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

The list of codes and corresponding types of devices (Commission implementing regulation (EU) 2017/2185)

A. Active devices

MDA CODE	Active implantable devices
MDA 0101	Active implantable devices for stimulation/inhibition/monitoring
MDA 0102	Active implantable devices delivering drugs or other substances
MDA 0103	Active implantable devices supporting or replacing organ functions
MDA 0104	Active implantable devices utilising radiation and other active implantable devices
MDA CODE	**Active non-implantable devices for imaging, monitoring and/or diagnosis**
MDA 0201	Active non-implantable imaging devices utilising ionizing radiation
MDA 0202	Active non-implantable imaging devices utilising non-ionizing radiation
MDA 0203	Active non-implantable devices for monitoring of vital physiological parameters
MDA 0204	Other active non-implantable devices for monitoring and/or diagnosis
MDA CODE	**Active non-implantable therapeutic devices and general active non-implantable devices**
MDA 0301	Active non-implantable devices utilising ionizing radiation
MDA 0302	Active non-implantable devices utilising non-ionizing radiation
MDA 0303	Active non-implantable devices utilising hyperthermia/hypothermia
MDA 0304	Active non-implantable devices for shock-wave therapy (lithotripsy)
MDA 0305	Active non-implantable devices for stimulation or inhibition
MDA 0306	Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis
MDA 0307	Active non-implantable respiratory devices
MDA 0308	Active non-implantable devices for wound and skin care
MDA 0309	Active non-implantable ophthalmologic devices
MDA 0310	Active non-implantable devices for ear, nose and throat
MDA 0311	Active non-implantable dental devices

MDA 0312	Other active non-implantable surgical devices
MDA 0313	Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport
MDA 0314	Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
MDA 0315	Software
MDA 0316	Medical gas supply systems and parts thereof
MDA 0317	Active non-implantable devices for cleaning, disinfection and sterilisation
MDA 0318	Other active non-implantable devices

B. Non-active devices

MDN CODE	Non-active implants and long term surgically invasive devices
MDN 1101	Non-active cardiovascular, vascular and neurovascular implants
MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1103	Non-active dental implants and dental materials
MDN 1104	Non-active soft tissue and other implants
MDN CODE	**Non-active non-implantable devices**
MDN 1201	Non-active non-implantable devices for anaesthesia, emergency and intensive care
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
MDN 1204	Non-active non-implantable devices for wound and skin care
MDN 1205	Non-active non-implantable orthopaedic and rehabilitation devices
MDN 1206	Non-active non-implantable ophthalmologic devices
MDN 1207	Non-active non-implantable diagnostic devices
MDN 1208	Non-active non-implantable instruments
MDN 1209	Non-active non-implantable dental materials
MDN 1210	Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing
MDN 1212	Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including *in vitro* fertilisation (IVF) and assisted reproductive technologies (ART)
MDN 1213	Non-active non-implantable devices composed of substances to be introduced into the human body *via* a body orifice or the dermal route
MDN 1214	General non-active non-implantable devices used in health care and other non-active non-implantable devices

Devices with specific characteristics

MDS CODE	Devices with specific characteristics
MDS 1001	Devices incorporating medicinal substances
MDS 1002	Devices manufactured utilising tissues or cells of human origin, or their derivatives
MDS 1003	Devices manufactured utilising tissues or cells of animal origin, or their derivatives
MDS 1004	Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council [(1)]
MDS 1005	Devices in sterile condition
MDS 1006	Reusable surgical instruments
MDS 1007	Devices incorporating or consisting of nanomaterial
MDS 1008	Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body
MDS 1009	Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices
MDS 1010	Devices with a measuring function
MDS 1011	Devices in systems or procedure packs
MDS 1012	Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745
MDS 1013	Class III custom-made implantable devices
MDS 1014	Devices incorporating as an integral part an *in vitro* diagnostic device

Devices for which specific technologies or processes are used

MDT CODE	Devices for which specific technologies or processes are used
MDT 2001	Devices manufactured using metal processing
MDT 2002	Devices manufactured using plastic processing
MDT 2003	Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)
MDT 2004	Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)
MDT 2005	Devices manufactured using biotechnology
MDT 2006	Devices manufactured using chemical processing
MDT 2007	Devices which require knowledge regarding the production of pharmaceuticals
MDT 2008	Devices manufactured in clean rooms and associated controlled environments
MDT 2009	Devices manufactured using processing of materials of human, animal, or microbial origin
MDT 2010	Devices manufactured using electronic components including communication devices
MDT 2011	Devices which require packaging, including labelling
MDT 2012	Devices which require installation, refurbishment
MDT 2013	Devices which have undergone reprocessing

Classification (Annex VIII Regulation 2017/745)

NON-INVASIVE DEVICES

Rule 1
All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

Rule 2
All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa:
- if they may be connected to a class IIa, class IIb or class III active device; or
- if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb.

In all other cases, such devices are classified as class I.

Rule 3
All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa.
All non-invasive devices consisting of a substance or a mixture of substances intended to be used *in vitro* in direct contact with human cells, tissues or organs taken from the human body or used *in vitro* with human embryos before their implantation or administration into the body are classified as class III.

Rule 4
All non-invasive devices which come into contact with injured skin or mucous membrane are classified as:
- class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
- class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;
- class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and
- class IIa in all other cases.

This rule applies also to the invasive devices that come into contact with injured mucous membrane.

INVASIVE DEVICES
Rule 5
All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:
- class I if they are intended for transient use;
- class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and
- class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

Rule 6
All surgically invasive devices intended for transient use are classified as class IIa unless they:
- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- are reusable surgical instruments, in which case they are classified as class I;
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or
- are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

Rule 7
All surgically invasive devices intended for short-term use are classified as class IIa unless they:
- are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III;
- are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb;
- have a biological effect or are wholly or mainly absorbed in which case they are classified as class III;
- are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or
- are intended to administer medicines, in which case they are classified as class IIb.

Rule 8
All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:
- are intended to be placed in the teeth, in which case they are classified as class IIa;
- are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III;
- have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;
- are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth;
- are intended to administer medicinal products, in which case they are classified as class III;
- are active implantable devices or their accessories, in which cases they are classified as class III;
- are breast implants or surgical meshes, in which cases they are classified as class III;

- are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or
- are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.

ACTIVE DEVICES

Rule 9

All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb.

All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb.

All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

Rule 10

Active devices intended for diagnosis and monitoring are classified as class IIa:

- if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;
- if they are intended to image *in vivo* distribution of radiopharmaceuticals; or
- if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

Rule 11

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

Rule 12

All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

Rule 13

All other active devices are classified as class I.

SPECIAL RULES

Rule 14

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.

Rule 15

All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb. All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb. This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

Rule 17

Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

Rule 18

All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non- viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

Rule 19

All devices incorporating or consisting of nanomaterial are classified as:

— class III if they present a high or medium potential for internal exposure;
— class IIb if they present a low potential for internal exposure; and
— class IIa if they present a negligible potential for internal exposure.

Rule 20
All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life- threatening conditions, in which case they are classified as class IIb.

Rule 21
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 are classified as:
— class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
— class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;
— class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and
— class IIb in all other cases.

Rule 22
Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III.

8. NOTES

Place and date*:*

For applicant :

Please fill the questionnaire in the electronic form, sign and return to the following address:

SIQ Ljubljana

Mašera-Spasićeva 10

SI - 1000 Ljubljana

☎ +386 1 4778 159 e-✉ mdr@siq.si
Fax: +386 1 4778 444 💻 http://www.siq.si

9. COMPLETED BY NOTIFIED BODY

Person responsible for reviewing the questionnaire (Project Leader (PL) and Final Reviewer (FR)):

_____ (PL)

_____ (FR)

_____ (FR)

_____ (FR)

Signature of MDR product manager:_____

9.1. To be filled in if there is a potential conflict of interest between the manufacturer of medical devices and the founder of the notified body (item 2.2. marked with "yes")

Founder (name of organization): _____ ☐ yes ☐ no

Type of connection (e.g. subsidiary, subcontractor, distributor, manufacturer, importer...):	
Additional explanations about the type of connection (and evidence):	
During the investigation of the potential conflict, the following were considered:	
Risk assessment with justification:	

Decision: Conflict of interest ☐ yes ☐ no

Signature of MDR product manager: _____

9.2. The product meets the definition of a medical device:

☐ yes ☐ no ☐ consult with the competent authorities

Notes:

MD * code and other knowledge (within the scope of the SIQ):

*(Commission Implementing Regulation (EU) 2017/2185 in MDCG 2019-14)

Appropriate classification of medical device:

☐ yes ☐ no ☐ consult with the competent authorities

Notes:

Appropriate conformity assessment procedure MP (MDR Annex): ☐ yes ☐ no

Notes:

The manufacturer has a subcontractor of critical processes, which will be included in the audit:

☐ yes ☐ no

List of locations for audit (justification):

The ability to provide the service: ☐ yes ☐ no

Annexes (e.g. opinion of an expert, detailed explanation of the classification, ...):

Place and date*:*

Signature of the person responsible for reviewing the questionnaire (PL, FR):