QUESTIONNAIRE ON MANUFACTURER, PRODUCTS AND ASSESSMENT ROUTE IN ACCORDANCE WITH THE MEDICAL DEVICE 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

a) MANUFACTURER

Name:

_____

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

_____

(Street, City, Postcode, Country)

Director (Name and surname):_____

Email director:_____

Contact person (Name and surname):_____

Phone:_____ Fax: _____ TAX Number:_____

Organization Email: _____ _____Web sites: _____

b) EU AUTHORIZED REPRESENTATIVE

Name:

_____

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

_____

(Street, City, Postcode, Country)

Director (Name and surname):_____

Email director:_____

Contact person (Name and surname):_____

Phone:_____ Fax: _____ TAX Number:_____

Organization Email: _____Web sites: _____

2. INFORMATION ABOUT THE COMPANY AND COMPANIES/MANUFACTURING SITES/ SUBCONTRACTORS RELATED TO THE PRODUCTS TO BE APPROVED

ID	Name and address (manufacturer, manufacturing sites, subcontractors)	Certificates (if any)	Employees	Activity performed by subcontractor
Manufacturing sites other than legal address: ☐ yes ☐ no Subcontractors: ☐ yes ☐ no				
Manufacturing sites:				
1				
2				
3				
Subcontractors**: ***Examples of activities performed by subcontractor: Design and development, Production, Packing / assembling in case of Systems and procedure packs, Sterilization process….*				
1				
2				
3				

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

Type of sterilization process used (if relevant):
Steam: ☐ yes ☐ no
EtO: ☐ yes ☐ no
Radiation: ☐ yes ☐ no

3. CERTIFICATION SCOPE

Statistical Classification of Economic Activities (NACE Rev. 2). Please state the code(s) and the name(s) of the activity(ies).	
Please state the activities and products/services that are covered by the management system and will be subject to certification.	
Please state any other activities and products/services that are excluded from certification.	

4. MANAGEMENT SYSTEMS

Please indicate the standard(s) for certification (*there is an annex to be filled in)

☐ISO 9001 ☐ISO 14001 ☐BS OHSAS 18001 *☐ISO 13485:2003 *☐HACCP

*☐ISO/IEC 27001 ☐ISO 50001 *☐IATF 16949 ☐ISO 13485:2016 *☐ISO 22000

☐EMAS ☐_____

Integration of the management system – please indicate common elements (to be filled-in in case of certification according to more standards)

☐ documentation ☐ management review ☐ internal audits ☐ policy and objectives

☐ processes ☐ corrective/preventive actions ☐ responsibilities

5. AUDITING

Data on a management system(s) certified by any other certification body(ies).

Standard _____ Cert. body _____ Year of certification _____

Desired date of a certification procedure: _____

6. CERTIFICATION SCOPE

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

7. PERSONNEL INVOLVED IN THE ESTABLISHMENT OF THE MANAGEMENT SYSTEM

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

8. PRODUCTS TO BE APPROVED

(relevant in relation of issuing EU certificate)

ID	Product group / Product Name	Note*	Classification (according to Annex VIII of the regulation 2017/745 on medical devices)	
			class	rule
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	

Technical file and clinical evaluation

Number of technical files
Number of clinical evaluations
Documentation language: ☐ English ☐ German ☐ Croatian ☐ Other:.....

9. ASSESSMENT ROUTE APPLIED FOR

(relevant in relation of issuing EU certificate)

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

10. 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 products:	
Batch identification:	
Batch size:	
Production testing according to which standard(s):	

11. 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.

Classification (Annex XIII 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.

12. NOTES

Place and date*:*

For applicant :

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

Slovenian Institute of Quality and Metrology

Tržaška cesta 2

SI-1000 Ljubljana, Slovenia

☎	+386 1 4778 149	e-✉	urejenost@siq.si
Fax:	+386 1 4778 444	💻	http://www.siq.si

13. COMPLETED BY NOTIFIED BODY

Client's administrator: _____ Signature of MDR product manager:_____

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):

**(NBOG WD 2017-2)*

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 (eg. opinion of an expert, detailed explanation of the classification, ...):

Place and date*:*

Signiture of client's administrator: