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| **VPRAŠALNIK O ORGANIZACIJI, PROIZVODIH TER O ŽELENEM POSTOPKU OCENITVE USTREZNOSTI GLEDE NA DIREKTIVO 93/42/EGS MDD\* O MEDICINSKIH PRIPOMOČKIH** |

\*Direktiva 93/42/EGS o medicinskih pripomočkih (MDD) z vsemi veljavnimi spremembami in dopolnitvami (Direktiva 2007/47/ES).

**1. SPLOŠNO O ORGANIZACIJI – PROIZVAJALCU IN/ALI POOBLAŠČENEM PREDSTAVNIKU**

**a) PROIZVAJALEC**

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| **Naziv**:    (Navedite skrajšan naziv kot je zapisan na registraciji organizacije na sodišču.)    (Ulica in hišna št., pošta, kraj)  Direktor (Ime in priimek):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  E-pošta direktorja:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Kontaktna oseba (Ime in priimek):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Telefon: Telefaks: Davčna številka:  E- pošta organizacije: \_\_\_\_\_\_\_\_\_Spletne strani: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**b) POOBLAŠČENI PREDSTAVNIK V EU**

**Naziv**:

(Navedite skrajšan naziv kot je zapisan na registraciji organizacije na sodišču.)

(Ulica in hišna št., pošta, kraj)

**2. PODATKI O PROIZVAJALCU IN PROIZVAJALCIH/PROIZVODNIH MESTIH/PODPOGODBENIKIH, POVEZANIH S PROIZVODI V POSTOPKU CERTIFICIRANJA:**

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| --- | --- | --- | --- | --- |
| ID | Naziv in naslov  (proizvajalca, proizvodnega mesta / lokacij proizvodnje, podpogodbenika) | Certifikati (če obstajajo) | Število zaposlenih | Proces, ki ga izvaja  podpogodbenik |
| Druge lokacije proizvodnje, če proizvodnja ni na naslovu organizacije:  da  ne  Podizvajalci :  da  ne | | | | |
| Navesti lokacije proizvodnje: | | | | |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| Navesti podizvajalce\*\*:  \*\**primeri procesov, ki jih izvaja podizvajalec: Načrtovanje in razvoj, Proizvodnja, Pakiranje / Združevanje medicinskih pripomočkov v primeru Sistemov in Paketov, Sterilizacija….* | | | | |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

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| Uporabljena metoda / postopek sterilizacije (če je to relevantno): |
| Para:  da  ne |
| EtO: da  ne |
| Radiacija:  da  ne |

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| **Priložite morebitno informativno gradivo o vaši organizaciji (osebna izkaznica, letno poročilo, prodajni katalog, ...)** |

**3. PROIZVODI ZAJETI V OBSEG CERTIFICIRANJA:**

(relevantno v zvezi z izdajo ES certifikata)

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| --- | --- | --- | --- | --- |
| ID | Kategorija proizvoda /ime proizvoda | Opomba\* | Razvrstitev v skladu z dodatkom IX direktive 93/42/EGS o medicinskih pripomočkih | |
| razred | pravilo |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |

*\*: tkivo živalskega izvora, zdravilo, derivat človeške krvi/plazme, nanomateriali*

**Opis in namen uporabe medicinskega pripomočka**

|  |  |
| --- | --- |
| ID | Opis medicinskega pripomočka |
| 1 |  |
| 2 |  |
| 3 |  |
| ID | Indikacije medicinskega pripomočka in namen uporabe |
| 1 |  |
| 2 |  |
| 3 |  |

**Tehnična mapa in klinična evalvacija**

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| Število tehničnih map |
| Število kliničnih evalvacij |
| **Jezik dokumentacije:**  slovenski  hrvaški  angleški  nemški  drugo:................................. |

**4. POSTOPEK UGOTAVLJANJA USTREZNOSTI:**

(relevantno v zvezi z izdajo ES certifikata)

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| **Razred proizvoda** | **Postopek ocenjevanje skladnosti:\*\*** | |  |
| Proizvod(i) razreda Is |  | | Opomba: Proizvodi razreda I, razen sterilnih in tistih z merilno funkcijo, ne zahtevajo posredovanja priglašenega organa |
| Proizvod(i) razreda Im |  | |
| Proizvod(i) razreda IIa |  | |
| Proizvod(i) razreda IIb |  | |
| Proizvod(i) razreda III |  | |
| *\*\*Priloga II (Celovit sistem za zagotavljanje kakovosti)*  *Priloga V (Zagotavljanje kakovosti proizvodnje)*  *Priloga VI (Zagotavljanje kakovosti izdelka)* | | *Priloga III (Tipski pregled vzorca)*  *Priloga IV (ES Overjanje)* | |

**5. SPLOŠNO O ZAHTEVAH GLEDE NA DODATEK IV DIREKTIVE 93/42/EGS MDD** (izpolnite le v primeru izbranega postopka po **Prilogi IV)**

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| Želena metoda overjanja: |  |
| Serija/lot ali serijske številke proizvodov: |  |
| Identifikacija serije: |  |
| Velikost serije: |  |
| Preskušanje v proizvodnji glede na kateri standard: |  |

**6. OPOMBE IN DODATNE INFORMACIJE**

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| **‘Medical device’** means any **instrument, apparatus, appliance, software, material or other article,** whether used alone or in combination, **including the software intended by its manufacturer** to be used specifically for diagnostic and/or therapeutic purposes andnecessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:  — diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensationfor an injury or handicap,  — investigation, replacement or modification of the anatomy or of a physiological process,  — control of conception,  and **which does not achieve its principal intended action** in or on the human **body by pharmacological, immunological or metabolic means, b**ut which may be assisted in its function by such means. | |
| **Classification (Annex IX 93/42/EEC)**  **Non-invasive devices**  **Rule 1**  All **non-invasive devices** are in 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 or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:  — if they may be connected to an active medical device in Class IIa or ahigher class,  — if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I.  **Rule 3**  All **non-invasive devices** intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.  **Rule 4**  All **non-invasive devices** which come into contact with injured skin:  — are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,  — are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,  — are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.  **Invasive devices**  **Rule 5**  All **invasive devices** with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I:  — are in Class I if they are intended for transient use,  — are in 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 a nasal cavity, in which case they are in Class I,  — are in 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 a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.  All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.  **Rule 6**  All **surgically invasive devices** intended for transient use are in 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 these parts of the body, in which case they are in Class III,  — reusable surgical instruments, in which case they are in Class I,  — intended specifically for use in direct contact with the | central nervous system, in which case they are in Class III,  — intended to supply energy in the form of ionising radiation in which case they are in Class IIb,  — intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,  — intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.  **Rule 7**  All **surgically invasive devices** intended for short-term use are in Class IIa unless they are intended:  — either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,  — or specifically for use in direct contact with the central nervous system, in which case they are in Class III,  — or to supply energy in the form of ionizing radiation in which case they are in Class IIb,  — or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,   * or to undergo chemical change in the body, except if the   devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.  **Rule 8**  All **implantable devices** and long-term surgically invasive devices are in Class IIb unless they are intended:  — to be placed in the teeth, in which case they are in Class IIa,  — to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,  — to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,  — or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.  **Additional rules applicable to active devices**  **Rule 9**  All **active therapeutic devices** intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from 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 in Class IIb.  All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.  **Rule 10**  **Active devices intended for diagnosis** are in Class IIa:  — if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,  — if they are intended to image *in vivo* distribution of radiopharmaceuticals,  — 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, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb. |
| Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.  **Rule 11**  All **active devices** intended to administer and/or remove medicines, body liquids or other substances to or from the body are in 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 andof the mode of application in which case they are in Class IIb.  **Rule 12**  All **other active devices** are in Class I.  **Special Rules**  **Rule 13**  All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.  All devices incorporating, as an integral part, a human blood derivative are in Class III. | **Rule 14**  All devices used for **contraception** or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.  **Rule 15**  All devices intended specifically to be used for **disinfecting, cleaning, rinsing** or, when appropriate, **hydrating contact lenses** are in Class IIb.  All devices intended specifically to be used **for disinfecting** medical devices are in Class IIa.Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb.  This rule does not apply to products that are intended to clean medicaldevices other than contact lenses by means of physical action.  **Rule 16**  Devices specifically intended for **recording of X-ray** diagnostic images are in Class IIa.  **Rule 17**  All devices manufactured **utilizing animal tissues** or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.  **Rule 18**  By derogation from other rules, blood bags are in Class IIb. |

**7. OPOMBE**

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| Kraj in datum*:* |
| **Za naročnika:** |
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| Vprašalnik, prosimo, izpolnite v elektronski obliki, podpišite in vrnite na naslov: | | | |
| **SIQ Ljubljana** | | | |
| **Mašera-Spasićeva ulica 10**  **SI - 1000 Ljubljana** | | | |
| 🕿 | 01 4778 149 | e-🖂 | urejenost@siq.si |
| Faks: | 01 4778 444 | 🖳 | http://www.siq.si |

**8. IZPOLNI PRIGLAŠENI ORGAN**

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| **Proizvod ustreza definiciji medicinskega pripomočka:**  da  ne  posvet s pristojnim organom  Opombe:  **MD koda \* in ostala znanja (znotraj obsega imenovanja SIQ):**  *\*(NBOG BPG 2009-3)*  **Ustrezna klasifikacija** **MP:**  da  ne  posvet s pristojnim organom  Opombe:  **Ustrezen postopek ugotavljanja skladnosti MP (Priloga MDD):**  da  ne  Opombe:  **Proizvajalec ima poddobavitelja kritičnih procesov, ki bo vključen v presojo:**  da  ne  Seznam lokacij za presojo (utemeljitev):  **Zmožnost za izvedbo storitve:**  da  ne  **Priloge** (Npr. mnenje strokovnega sodelavca, podrobnejša obrazložitev klasifikacije,…)**:**   |  | | --- | | Kraj in datum*:* | | **Za SIQ odobril:** | |