PRIJAVA za akreditacijo CERTIFIKACIJSKEGA ORGANA

ZA CERTIFICIRANJE SISTEMOV VODENJA  
Application for accreditation of certification body for management systems

**Izpolnjeno in podpisano prijavo pošljite na SA po navadni ali elektronski pošti. Prijavo potrebujemo tudi v Word formatu, zato nam jo prosim posredujte po elektronski pošti, in sicer prijavo za pridobitev akreditacije na naslov** [**info@slo-akreditacija.si**](mailto:info@slo-akreditacija.si)**, prijavo za širitev pa vašemu koordinatorju.** **Če prijavljate širitev obsega akreditacije, lahko izpolnite le tiste rubrike, ki so specifične za prijavljeno širitev. */*** *The completed and signed application form send by ordinary mail or e-mail. Please send us application form also in Word format by e-mail – initial application to info@slo-akreditacija.si and application for extension of scope to your coordinator. If you are applying for an extension of accreditation scope, you can only fill in those sections that are specific to the registered extension.*

**VRSTA PRIJAVE / Type of application**:

pridobitev akreditacije / initial application

|  |  |
| --- | --- |
| Identifikacijska številka akreditacije / *Accreditation ID no.*: |  |

spremembe pri že akreditirani shemi certificiranja / changes to already accredited certification scheme

širitev obsega akreditacije / extension of accreditation scope:

nova področja v okviru že akreditirane sheme / *new fields within already accredited schemes*

širitev na drugo shemo certificiranja / *extension to another certification scheme*

vključitev drugih lokacij / *inclusion of other sites*

# SPLOŠNI PODATKI O PRIJAVITELJU / General data about the applicant

|  |  |
| --- | --- |
| **Naziv organizacije** / *Company* name |  |
| Naslov / Address |  |
| Matična številka / Registration No. |  |
| Davčna številka / VAT No. |  |
| Naslov za pošiljanje računa / Invoicing Address |  |
| Številka TRR / Account No. |  |
| Odprt pri banki / Opened at Bank |  |
| Telefon / Phone |  |
| Ime in priimek pravnega zastopnika / Name and surname of Legal Representative |  |
| Funkcija/položaj pravnega zastopnika / Function/position of Legal Representative |  |

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| --- | --- |
| **Naziv certifikacijskega organa /** *Name of certification body* |  |
| Naslov / Address |  |
| Telefon / Phone |  |

|  |  |
| --- | --- |
| **Kontaktna oseba /** *Contact Person*  (Ime in priimek / *Name and Surname*) |  |
| Položaj, funkcija / Position, function |  |
| Naslov / Address |  |
| Telefon / Phone |  |
| Elektronski naslov / E-mail Address |  |

# PRAVNA IDENTITETA, POLOŽAJ, ORGANIZACIJA / Legal identity, position, organization

## Pravni status prijavitelja/nosilca akreditacije (pravna oseba) je / *The legal status of the applicant/ accreditation holder (legal entity)* is:

javna ali zasebna gospodarska družba / public or private business company

javni ali zasebni zavod / public or private institute

državni organ / *governmental authority*

samostojni podjetnik / sole trader

drugo (opišite) / other (describe)

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|  |

Nosilec dejavnosti za akreditacijo je / *Accreditation activity holder is*:

neposredno pravna oseba / directly legal entity

ena ali več notranjih organizacijskih enot, oddelkov, sektorjev / *one or more internal organizational units, departments, sectors*

podružnica, poslovna enota / branch office, business unit

drugo (opišite) / other (describe)

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|  |

Dejavnost za akreditacijo se izvaja za / *The* accreditation activity is performed for:

notranjega naročnika (lastno organizacijo) / internal client (own company)

zunanjega naročnika / external client

## Opišite razloge za pridobitev akreditacije za prijavljeni obseg oziroma posamezne dele obsega. V primeru, da je akreditacija pogoj za pridobitev pooblastila/imenovanja, ga navedite in opredelite, na katere dele prijavljenega obsega se to nanaša. / *Please describe the reasons for obtaining accreditation for the applied scope or individual parts of the scope. If accreditation is a condition for obtaining the authorization/appointment, please specify it and identify to which parts of the applied scope this refers.*

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## Opišite organizacijsko strukturo certifikacijskega organa in položaj dejavnosti certificiranja v organizaciji (priložite organizacijski diagram). / *Please* describe organizational structure of the certification body and the position in the company (attach organizational chart).

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## Navedite pravne subjekte, s katerimi ima certifikacijski organ lastniške, finančne, upravljavske in druge povezave oziroma subjekte, ki so pod organizacijskim nadzorom certifikacijskega organa ter njihove dejavnosti. / *Please indicate the legal entities with which the certification body has ownership, financial, governmental or other relationships, or entities that are under the organizational control of the certification body and their activities.*

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## Opišite, kakšna je povezava med dejavnostjo certificiranja sistemov vodenja in drugimi dejavnostmi certifikacijskega organa (priložite izpis dejavnosti iz sodnega registra). / *Please* describe *the relationship between certification and any other activities in which certification body is engaged* (attach extract of activities from judicial record).

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# SISTEM VODENJA KAKOVOSTI / Quality management system

## Kdaj je bil v certifikacijskem organu vpeljan sistem vodenja kakovosti po zahtevah standarda SIST EN ISO/IEC 17021-1? / When was the quality management system according to standard SIST EN ISO/IEC 17021-1 implemented in the certification body?

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## Ali je certifikacijski organ že akreditiran / v postopku pridobivanja akreditacije v skladu s standardom SIST EN ISO/IEC 17021-1 katerega drugega akreditacijskega organa? / *Is the certification body accredited / in process of gaining accreditation in accordance with the standard SIST EN ISO 17021-1 of some other accreditation body?*

DA / YES  NE / NO

Če je odgovor da, navedite, v okviru katere akreditacijske službe in za katera področja certificiranja (lahko priložite dokument, ki podaja obseg akreditacije). / *If yes, please indicate the accreditation body and scope of accreditation (you may attach a document that provides a scope of accreditation).*

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|  |

# OSEBJE / Personnel

## Vodja certificiranja (izpolniti prilogo 1) / *Head of certification (fill in Annex 1)*

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| --- |
|  |

## Namestnik vodje (izpolniti prilogo 1) / *Deputy of head (fill in Annex 1)*

|  |
| --- |
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## Število ostalega osebja certifikacijskega organa, ki sodeluje pri certificiranju (po posamični shemi certificiranja, če je relevantno) / *Number of other personnel of the certification body, which participate in certification activities (by individual certification scheme, if relevant):*

|  |  |  |
| --- | --- | --- |
|  | | Število osebja / Number of personnel |
| Shema / *Scheme*: |  | |
| - zaposleni v certifikacijskem organu / *employed by certification body* | |  |
| - pogodbeno zaposleni (presojevalci) / *contracted personnel (auditors)* | |  |
| Shema / *Scheme*: |  | |
| - zaposleni v certifikacijskem organu / *employed by certification body* | |  |
| - pogodbeno zaposleni (presojevalci) / *contracted personnel (auditors)* | |  |
| skupno / total | |  |

## Ali je osebje (presojevalci) usposobljeno, da kompetentno pokriva vsa področja certificiranja (EA in NACE področja), na katera se nanaša prijava za akreditacijo? (priložiti seznam presojevalcev z informacijo o področju, ki ga posameznik pokriva, in o kategorizaciji) / *Is the personnel (auditors) trained to competently cover all areas of certification (EA and NACE codes) referred to in the application for accreditation? (attach a list of auditors with information about the area, which covers the individual, and on the categorization)*

DA / YES  NE / NO

# LOKACIJE / Sites

## Lokacije (v Sloveniji in/ali v tujini), kjer izvajate aktivnosti postopka certificiranja iz prijavljenega obsega akreditacije (npr. prejem prijave, pregled prijave, odločanje o presojevalcih …). Podajte informacije za lokacije ne glede na to, za kakšno pravno obliko gre (npr. pravna oseba, podpogodbeno razmerje z izvajalcem, predstavništvo, zastopnik). / Sites (in Slovenia and/or foreign) where certification activities are performed for applied accreditation scope (e.g. receipt of the application, review of application, decision-making on auditors …). Please state the sites regardless of their legal form (e.g. legal entity, sub-contractual relationship with operator, representation, agency).

|  |  |
| --- | --- |
| Naziv in naslov lokacije /  Name and address of site | Aktivnosti postopka certificiranja, ki se jih tam izvaja /  Activities of the certification process carried out there |
|  |  |
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## Pravni subjekti (predstavništvo, agencija, franšiza, prodajna pisarna), od koder se izvajajo in/ali vodijo aktivnosti v postopku certificiranja v imenu certifikacijskega organa / Legal entities (representative, agency, franchisee, sales office) performing and/or managing certification activities on behalf of certification body:

|  |  |  |  |
| --- | --- | --- | --- |
| Pravni subjekt /  Legal entity | Naslov /  Address | Pravni status /  Legal Status | Aktivnosti certificiranja / Certification Activities |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Ali se za katero od vaših strank/naročnikov izvaja certificiranje/presojanje iz prijavljenega obsega akreditacije v tujini (npr. na lokaciji stranke/naročnika oziroma na terenu)? / *Is certification/audit from the applied scope of accreditation carried out for any of your clients abroad (e.g. at the client's location or in the field)?*

ne / *no*

da / *yes*

|  |  |
| --- | --- |
| Država, v kateri izvajate presoje / Country in which you are auditing | Področja akreditirane dejavnosti\*, ki se jih tam izvaja /  Fields of accredited activities\* carried out in this country |
|  |  |
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\* pri navedbi področij izhajajte iz opredelitev v dokumentu D05-11 oz. v vaši Prilogi k akreditacijski listini / *for specifying fields of accreditation activities see the definitions in the document D05-11 or in your Annex to Accreditation Certificate*

# PODPOGODBENIKI / *Outsourcing*

## Ali certifikacijski organ oddaja del dejavnosti certificiranja (npr. izvajanje presoj) drugemu organu? */ Does the certification body subcontract to another organization to provide part of the certification activity on behalf of certification body (e.g. audit performance)?*

DA / YES  NE / NO

Če je odgovor da, prosimo, da navedete, katere aktivnosti v postopku certificiranja izvajajo vaši podpogodbeniki, kateri so vaši podpogodbeniki in kako ugotavljate njihovo usposobljenost. / *If yes, please, list the activities that certification body subcontract, your subcontractors and describe how does certification body verify subcontractor’s competence.*

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# PRIJAVLJENI OBSEG AKREDITACIJE / *Scope applied for accreditation*

**Navodila / *Instructions***

Pri opredelitvi obsega upoštevajte določila dokumentov S14 – Obseg akreditacije in S14d2 – Obseg akreditacije pri certifikacijskih organih in preveriteljih. / *In specifying the scope, please observe the provisions of the documents S14 – Scope of accreditation and S14d2 – Scope of accreditation in certification bodies and verifiers.*

Navedite **naslov lokacije** (v Sloveniji ali v tujini), kjer se dejavnost izvaja. Če se aktivnosti certificiranja izvajajo na različnih lokacijah, tudi če so te del iste organizacije, podajte ločen seznam za vsako od lokacij. / *Please indicate the address of the site (in Slovenia or another country) at which the activity is performed. When the certification activities are performed at different sites, even if they are part of the same organization, provide a separate list for each location.*

V spodnjih tabelah jasno in nedvoumno definirajte oziroma označite obseg želene akreditacije. / *In the tables below, clearly and unambiguously define or indicate the scope of the desired accreditation.*

Prosimo, da v poševni pisavi dodate tudi angleški prevod besedila. */ Please add also the English translations of text and use italics format.*

# Navedite naslov lokacije, kjer se izvajajo aktivnosti / *State site address where activities are performed*

## Certificiranje sistemov vodenja kakovosti (SIST EN ISO 9001), certificiranje sistemov ravnanja z okoljem (SIST EN ISO 14001) in certificiranje sistemov vodenja varnosti in zdravja pri delu (SIST ISO 45001) / *Certification of quality management systems (SIST EN ISO 9001), certification of environmental management systems (SIST EN ISO 14001), and certification of occupational health and safety management systems (SIST ISO 45001)*

Označite sheme certificiranja in področja certificiranja, za katera želite pridobiti akreditacijo (po posamični shemi). / *Indicate certification scheme and fields for which certification body likes to be accredited (by separate scheme).*

| **ISO 9001** | **ISO 14001** | **ISO 45001** | **Klasifikacija EAC** / *EAC classification* | **Klasifikacija NACE** */ NACE classification* | **Gospodarska dejavnost** / *Economic sector* |
| --- | --- | --- | --- | --- | --- |
|  |  |  | 1 | 01, 02, 03 | Kmetijstvo, gozdarstvo in ribištvo  *Agriculture, forestry and fishing* |
|  |  |  | 2 | 05, 06, 07, 08, 09 | Rudarstvo in kamnolomstvo  *Mining and quarrying* |
|  |  |  | 3 | 10, 11, 12 | Živilski izdelki, pijače in tobak  *Food products, beverages and tobacco* |
|  |  |  | 4 | 13, 14 | Tekstil in tekstilni izdelki  *Textiles and textile products* |
|  |  |  | 5 | 15 | Usnje in usnjeni izdelki  *Leather and leather products* |
|  |  |  | 6 | 16 | Les in izdelki iz lesa  *Wood and wood products* |
|  |  |  | 7 | 17 | Celuloza, papir in izdelki iz papirja  Pulp, paper and paper products |
|  |  |  | 8 | 58.1, 59.2 | Založniške družbe  *Publishing companies* |
|  |  |  | 9 | 18 | Tiskarska podjetja  *Printing companies* |
|  |  |  | 10 | 19 | Proizvodnja koksa in rafiniranih naftnih derivatov  *Manufacture of coke and refined petroleum products* |
|  |  |  | 11 | 24.46 | Jedrsko gorivo  *Nuclear fuel* |
|  |  |  | 12 | 20 | Kemikalije, kemični izdelki in vlakna  *Chemicals, chemical products and fibres* |
|  |  |  | 13 | 21 | Farmacevtski izdelki  *Pharmaceuticals* |
|  |  |  | 14 | 22 | Izdelki iz gume in plastike  *Rubber and plastic products* |
|  |  |  | 15 | 23, razen/*except* 23.5 in/*and* 23.6 | Nekovinski mineralni izdelki  *Non-metallic mineral products* |
|  |  |  | 16 | 23.5, 23.6 | Beton, cement, apno, ometi ipd.  *Concrete, cement, lime, plaster etc.* |
|  |  |  | 17 | 24, razen/*except* 24.46,  25, razen/*except* 25.4, 33.11 | Osnovne kovine in gotovi kovinski izdelki  *Basic metals and fabricated metal products* |
|  |  |  | 18 | 25.4, 28, 30.4, 33.12, 33.2 | Stroji in oprema  *Machinery and equipment* |
|  |  |  | 19 | 26, 27, 33.13, 33.14, 95.1 | Električna in optična oprema  *Electrical and optical equipment* |
|  |  |  | 20 | 30.1, 33.15 | Ladjedelništvo  *Shipbuilding* |
|  |  |  | 21 | 30.3, 33.16 | Zračna in vesoljska plovila  *Aerospace* |
|  |  |  | 22 | 29, 30.2, 30.9, 33.17 | Druga transportna oprema  *Other transport equipment* |
|  |  |  | 23 | 31, 32, 33.19 | Proizvodnja, ki ni uvrščena drugje  *Manufacturing not elsewhere classified* |
|  |  |  | 24 | 38.3 | Recikliranje  *Recycling* |
|  |  |  | 25 | 35.1 | Oskrba z električno energijo  *Electricity supply* |
|  |  |  | 26 | 35.2 | Oskrba s plinom  *Gas supply* |
|  |  |  | 27 | 35.3, 36 | Oskrba z vodo  *Water supply* |
|  |  |  | 28 | 41, 42, 43 | Gradbeništvo  *Construction* |
|  |  |  | 29 | 45, 46, 47, 95.2 | Trgovina na debelo in drobno, popravila motornih vozil, motornih koles ter osebnih in gospodinjskih potrebščin  *Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods* |
|  |  |  | 30 | 55, 56 | Hoteli in restavracije  *Hotels and restaurants* |
|  |  |  | 31 | 49, 50, 51, 52, 53, 61 | Transport, skladiščenje in komunikacije  *Transport, storage and communication* |
|  |  |  | 32 | 64, 65, 66, 68, 77 | Finančno posredništvo, nepremičnine, najem  *Financial intermediation; real estate; renting* |
|  |  |  | 33 | 58.2, 62, 63.1 | Informacijska tehnologija  *Information technology* |
|  |  |  | 34 | 71, 72,  74, razen/*except* 74.2 in/*and* 74.3 | Inženirske storitve  *Engineering services* |
|  |  |  | 35 | 69, 70, 73, 74.2, 74.3, 78, 80, 81, 82 | Druge storitve  *Other services* |
|  |  |  | 36 | 84 | Javna uprava  *Public administration* |
|  |  |  | 37 | 85 | Izobraževanje  *Education* |
|  |  |  | 38 | 75, 86, 87, 88 | Zdravstveno in socialno varstvo  *Health and social work* |
|  |  |  | 39 | 37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96 | Druge socialne storitve  *Other social services* |

## Certificiranje sistemov vodenja kakovosti (SIST EN ISO 9001), upoštevajoč HACCP / *Certification of quality management systems (SIST EN ISO 9001) including HACCP*

Označite področja, za katera želite pridobiti akreditacijo. / *Indicate fields for which certification body likes to be accredited.*

|  |  |  |
| --- | --- | --- |
| **Področje aktivnosti** / *Field of activity* | | **Omejitve** / *Limitations* |
|  | Pridelava / *Production* |  |
|  | Predelava živil in krme / *Food and feed processing* |  |
|  | Oskrba z živili in pijačo / *Food and beverage supply* |  |
|  | Trgovina, transport, skladiščenje / *Trade, transport, storage* |  |
|  | Pomožne storitve / *Auxiliary services* |  |
|  | Proizvodnja biokemičnih snovi / *Production of biochemical substances* |  |

## Certificiranje sistemov vodenja kakovosti v skladu z uredbami o statusu odpadkov\* / *Certification of quality management systems according to End of Waste Regulations\**

*\** Opomba */ Note:*

Akreditacija po Uredbi (EU) št. 333/2011, člen 6, je možna, če je certifikacijski organ že akreditiran ali je vložil prijavo za akreditacijo za certificiranje sistemov kakovosti po ISO 9001 za IAF/EA področji 17 ali 24. / *Accreditation under Regulation (EU) No. 333/2011 Article 6, is possible if the certification body is already accredited or has applied for accreditation of quality management systems according to ISO 9001 for the IAF/EA fields 17 or 24.*

Akreditacija po Uredbi (EU) št. 715/2013, člen 5, je možna, če je certifikacijski organ že akreditiran ali je vložil prijavo za akreditacijo za certificiranje sistemov kakovosti po ISO 9001 po NACE kodi 38 ali 24 (vključena podkoda 24.44). / *Accreditation under Regulation (EU) No. 715/2013 Article 5, is possible if the certification body is already accredited or has applied for accreditation of quality management systems according to ISO 9001 for the NACE codes 38 or 24 (subcode 24.44 included).*

Akreditacija po Uredbi (EU) št. 1179/2012, člen 5, je možna, če je certifikacijski organ že akreditiran ali je vložil prijavo za akreditacijo za certificiranje sistemov kakovosti po ISO 9001 po NACE kodi 38 ali 23.1. / *Accreditation under Regulation (EU) No. 1179/2012 Article 5, is possible if the certification body is already accredited or has applied for accreditation of quality management systems according to ISO 9001 for the NACE codes 38 or 23.1.*

Označite, za katere vrste odpadkov želite pridobiti akreditacijo. / *Indicate what types of scraps the certification body wants to obtain accreditation for.*

|  |  |  |
| --- | --- | --- |
| **Uredba** / *Regulation* | | **Vrsta odpadka** / *Types of scrap* |
|  | Uredba / *Regulation* (EU) št. / No. 333/2011 | odpadne kovine - odpadno železo, jeklo in aluminij  *metal scrap - waste iron, steel and aluminium* |
|  | Uredba / *Regulation* (EU) št. / No. 715/2013 | odpadni baker  *copper scrap* |
|  | Uredba / *Regulation* (EU) št. / No. 1179/2012 | odpadno steklo  *glass cullet* |

## Certificiranje sistemov vodenja kakovosti pri medicinskih pripomočkih (ISO 13485)\* / *Certification of quality management system for medical devices (ISO 13485)\**

*\** Opomba */ Note:*

Katerikoli drug proizvod, ki se ne uporablja za medicinske ali terapevtske namene (kot so kozmetika, zelišča, prehranska dopolnila, oprema za lepotenje itd.) ali ni neposredno povezan s preprečevanjem ali zdravljenjem osebe, ni mogoče opredeliti kot medicinski pripomoček. / *Any other product that does not have medical or therapeutic purposes (border line products, such as cosmetic, herbal, nutritional supplements, beauty equipment, etc.) or not directly connected to the prevention or restoration of the health state of the persons, cannot be classified as a medical device.*

Označite skupine proizvodov v okviru tehničnega področja, za katere želite pridobiti akreditacijo (IAF MD 8). / *Indicate what product categories (classification according to IAF MD 8) the certification body wants to obtain accreditation for.*

**NEAKTIVNI MEDICINSKI PRIPOMOČKI / *NON-ACTIVE MEDICAL DEVICES***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| Neaktivni medicinski pripomočki  ***Non-active medical devices*** | Splošni neaktivni medicinski pripomočki, ki niso za vsaditev  *General non-active, non-implantable medical devices* |  | Neaktivni pripomočki za anestezijo, urgentno in intenzivno oskrbo  *Non-active devices for anaesthesia, emergency and intensive care* |  |
|  | Neaktivni pripomočki za injiciranje, infuzijo, transfuzijo in dializo  *Non-active devices for injection, infusion, transfusion and dialyses* |  |
|  | Neaktivni pripomočki za ortopedijo in rehabilitacijo  *Non-active orthopedic and rehabilitation devices* |  |
|  | Neaktivni pripomočki za merilno funkcijo  *Non-active medical devices with measuring function* |  |
|  | Neaktivni oftalmološki pripomočki  *Non-active ophthalmologic devices* |  |
|  | Neaktivni instrumenti  *Non-active instruments* |  |
|  | Pripomočki proti zanositvi  *Contraceptive medical devices* |  |
|  | Neaktivni pripomočki za dezinfekcijo, čiščenje, izpiranje  *Non-active medical devices for disinfecting, cleaning, rinsing* |  |
|  | Neaktivni pripomočki za in vitro oploditev (IVF) in reproduktivna tehnologija (ART)  *Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)* |  |
|  | Neaktivni medicinski pripomočki za zaužitje  *Non-active medical devices for ingestion* |  |
| Neaktivni vsadki  *Non-active implants* |  | Neaktivnih kardiovaskularni vsadki  *Non-active cardiovascular implants* |  |
|  | Neaktivni ortopedski vsadki  *Non-active orthopedic implants* |  |
|  | Neaktivni funkcionalni vsadki  *Non-active functional implants* |  |
|  | Neaktivni vsadki mehkega tkiva  *Non*-active soft tissue implants |  |
| Pripomočki za oskrbo ran  *Devices for wound care* |  | Povoji in obveze za rane  *Bandages and wound dressings* |  |
|  | Material za šivanje in spone  *Suture material and clamps* |  |
|  | Drugi medicinski pripomočki za oskrbo ran  *Other medical devices for wound care* |  |
| Neaktivni zobozdravstveni pripomočki in oprema  *Non-active dental devices and accessories* |  | Neaktivni zobozdravstveni pripomočki/oprema in instrumenti  *Non-active dental devices/equipment and instruments* |  |
|  | Zobozdravstveni material  *Dental materials* |  |
|  | Zobni vsadki  *Dental implants* |  |
| Drugi neaktivni medicinski pripomočki\*\*  *Non-active medical devices other than specified above\*\** |  |  |  |

\*\* Ko certifikacijski organ zaprosi za pridobitev ali širitev akreditacije za označeno tehnično področje, priloži seznam medicinskih pripomočkov, njihovo klasifikacijo glede na tveganje ter kratko in jedrnato izjavo o nameravanem namenu uporabe medicinskega pripomočka. / *Where the CAB applies for a scope of accreditation for the indicated technical area, the CAB shall provide a list of medical devices including their risk classification and a concise statement of the intended purpose of the medical device.*

**AKTIVNI MEDICINSKI PRIPOMOČKI (NISO ZA VSADITEV) */ ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| Aktivni medicinski pripomočki (niso za vsaditev)  *Active medical devices (non-implantable)* | Splošni aktivni medicinski pripomočki  *General active medical* *devices* |  | Pripomočki za zunajtelesno cirkulacijo, infuzijo in hemaferezo  *Devices for extra-corporal circulation, infusion and haemopheresis* |  |
|  | Respiratorni pripomočki, vključno s hiperbaričnimi komorami za zdravljenje s kisikom, pripomočki za inhalacijsko anestezijo  *Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia* |  |
|  | Pripomočki za stimulacijo in inhibicijo  *Devices for stimulation or inhibition* |  |
|  | Aktivni kirurški pripomočki  *Active surgical devices* |  |
|  | Aktivni oftalmološki pripomočki  *Active ophthalmologic devices* |  |
|  | Aktivni zobozdravstveni pripomočki  *Active dental devices* |  |
|  | Aktivni pripomočki za dezinfekcijo in sterilizacijo  *Active devices for disinfection and sterilization* |  |
|  | Aktivni pripomočki za rehabilitacijo in aktivne proteze  *Active rehabilitation devices and active prostheses* |  |
|  | Aktivni pripomočki za pozicioniranje bolnika in transport  *Active devices for patient positioning and transport* |  |
|  | Aktivni pripomočki za in vitro oploditev (IVF) in reproduktivna tehnologija (ART)  *Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)* |  |
|  | Programska oprema, vključno z oblikovanjem programske opreme za medicinske pripomočke  *Software, including software design for medical devices* |  |
|  | Sistemi za oskrbo z medicinskimi plini in njihovimi deli  *Medical gas supply systems and parts thereof* |  |
| Pripomočki za slikanje  *Devices for imaging* |  | Pripomočki, ki uporabljajo ionizirajoče sevanje  *Devices utilizing ionizing radiation* |  |
|  | Pripomočki, ki uporabljajo neionizirajoče sevanje  *Devices utilizing non-ionizing radiation* |  |
| Pripomočki za nadzorovanje/monitoring  *Monitoring devices* |  | Pripomočki za nadzorovanje nevitalnih fizioloških parametrov  *Monitoring devices of non-vital physiological parameters* |  |
|  | Pripomočki za nadzorovanje vitalnih fizioloških parametrov  *Monitoring devices of vital physiological parameters* |  |
| Pripomočki za sevalno in termo terapijo  *Devices for radiation therapy and thermo- therapy* |  | Pripomočki, ki uporabljajo ionizirajoče sevanje  *Devices utilising ionizing radiation* |  |
|  | Pripomočki, ki uporabljajo neionizirajoče sevanje  *Devices utilising non-ionizing radiation* |  |
|  | Pripomočki za hipetermijo / hipotermijo  *Devices for hyperthermia / hypothermia* |  |
|  | Pripomočki za (ekstrakorporalno) terapijo z udarnimi valovi (litotripsija)  *Devices for (extracorporal) shockwave therapy (lithotripsy)* |  |
| Drugi aktivni medicinski pripomočki (niso za vsaditev)\*\*  *Active (non-implantable) medical devices other than specified above\*\** |  |  |  |

\*\* Ko certifikacijski organ zaprosi za pridobitev ali širitev akreditacije za označeno tehnično področje, priloži seznam medicinskih pripomočkov, njihovo klasifikacijo glede na tveganje ter kratko in jedrnato izjavo o nameravanem namenu uporabe medicinskega pripomočka. / *Where the CAB applies for a scope of accreditation for the indicated technical area, the CAB shall provide a list of medical devices including their risk classification and a concise statement of the intended purpose of the medical device.*

**VSADLJIVI AKTIVNI MEDICINSKI PRIPOMOČKI / *ACTIVE IMPLANTABLE MEDICAL DEVICES***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| Vsadljivi aktivni medicinski pripomočki  *Active implantable medical devices* | Splošni vsadljivi aktivni medicinski pripomočki  *General active implantable medical devices* |  | Aktivni medicinski pripomočki za stimulacijo / inhibicijo *Active implantable medical devices for stimulation / inhibition* |  |
|  | Aktivni medicinski pripomočki za vnašanje zdravil ali drugih snovi  *Active implantable medical devices delivering drugs or other substances* |  |
|  | *Aktivni medicinski pripomočki za nadomeščanje ali zamenjavo funkcij organov*  *Active implantable medical devices substituting or replacing organ functions* |  |
| Drugi vsadljivi medicinski pripomočki\*\*  *Implantable medical devices other than specified above\*\** |  |  |  |

\*\* Ko certifikacijski organ zaprosi za pridobitev ali širitev akreditacije za označeno tehnično področje, priloži seznam medicinskih pripomočkov, njihovo klasifikacijo glede na tveganje ter kratko in jedrnato izjavo o nameravanem namenu uporabe medicinskega pripomočka. / *Where the CAB applies for a scope of accreditation for the indicated technical area, the CAB shall provide a list of medical devices including their risk classification and a concise statement of the intended purpose of the medical device.*

**IN VITRO DIAGNOSTIČNI MEDICINSKI PRIPOMOČKI (IVD) / *IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVD)***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| In vitro diagnostični medicinski pripomočki  *In vitro diagnostic medical devices (IVD)* |  | Reagenti in reagenski proizvodi, kalibratorji in kontrolni materiali za:  klinično kemijo, imunokemijo (imunologijo), hematologijo/hemostazo/imunohemato-logijo, mikrobiologijo, infekcijsko imunologijo, histologijo/citologijo, genetsko testiranje  *Reagents and reagent products, calibrators and control materials for:*  *clinical chemistry, immunochemistry (immunology), haematology/haemostasis/ immunohematology, microbiology, infectious immunology, histology/cytology, genetic testing* |  |  |
|  | In vitro diagnostični instrumenti in programska oprema  *In vitro diagnostic instruments and software* |  |  |
|  | Drugi in vitro medicinski pripomočki\*\*  *IVD medical devices other than specified above\*\** |  |  |

\*\* Ko certifikacijski organ zaprosi za pridobitev ali širitev akreditacije za označeno tehnično področje, priloži seznam medicinskih pripomočkov, njihovo klasifikacijo glede na tveganje ter kratko in jedrnato izjavo o nameravanem namenu uporabe medicinskega pripomočka. / *Where the CAB applies for a scope of accreditation for the indicated technical area, the CAB shall provide a list of medical devices including their risk classification and a concise statement of the intended purpose of the medical device.*

**METODE STERILIZACIJE MEDICINSKIH PRIPOMOČKOV / *STERILIZATION METHODS FOR MEDICAL DEVICES***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| Metode sterilizacije medicinskih pripomočkov  *Sterilization methods for medical devices* |  | Sterilizacija s pomočjo etilen oksida  *Ethylene oxide gas sterilization (EOG)* |  |  |
|  | Vlažna sterilizacija  *Moist heat* |  |  |
|  | Obdelava v aseptičnem okolju  *Aseptic processing* |  |  |
|  | Radiološka sterilizacija (npr. gama, rentgensko sevanje, elektronski žarki) *Radiation sterilization (e.g. gamma, x-ray, electron beam)* |  |  |
|  | Parna in formaldehidna sterilizacija pri nizki temperaturi  *Low temperature steam and formaldehyde sterilization* |  |  |
|  | Termična sterilizacija s suho toploto  *Thermic sterilization with dry heat* |  |  |
|  | Sterilizacija z vodikovim peroksidom  *Sterilization with hydrogen*  *peroxide* |  |  |
|  | Druga sterilizacijska metoda  *Sterilization method other than specified above* |  |  |

**PRIPOMOČKI, KI VSEBUJEJO/UPORABLJAJO POSEBNE SNOVI/TEHNOLOGIJE / *DEVICES INCORPORATING/ UTILIZING SPECIFIC SUBSTANCES/TECHNOLOGIES***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| Pripomočki, ki vsebujejo/uporabljajo posebne snovi/ tehnologije  *Devices incorporating/utilizing specific substances/ technologies* |  | Medicinski pripomočki, ki vsebujejo zdravilne učinkovine  *Medical devices incorporating medicinal substances* |  |  |
|  | Medicinski pripomočki, ki uporabljajo tkiva živalskega izvora  *Medical devices utilizing tissues of animal origin* |  |  |
|  | Medicinski pripomočki, ki vsebujejo derivate človeške krvi  *Medical devices incorporating derivates of human blood* |  |  |
|  | Medicinski pripomočki, ki uporabljajo  mikromehaniko  *Medical devices utilizing micromechanics* |  |  |
|  | Medicinski pripomočki, ki uporabljajo  nanomateriale  *Medical devices utilizing nanomaterials* |  |  |
|  | Medicinski pripomočki, ki uporabljajo biološko aktivne premaze in / ali materiale ali ki se v celoti ali pretežno absorbirajo  *Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed* |  |  |
|  | Medicinski pripomočki, ki vsebujejo ali uporabljajo specifične snovi / tehnologije / elemente, razen zgoraj navedene\*\*  *Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above\*\** |  |  |

\*\* Ko certifikacijski organ zaprosi za pridobitev ali širitev akreditacije za označeno tehnično področje, priloži seznam medicinskih pripomočkov, njihovo klasifikacijo glede na tveganje ter kratko in jedrnato izjavo o nameravanem namenu uporabe medicinskega pripomočka. / *Where the CAB applies for a scope of accreditation for the indicated technical area, the CAB shall provide a list of medical devices including their risk classification and a concise statement of the intended purpose of the medical device.*

**DELI\*\*\* IN STORITVE / *PARTS\*\*\* AND SERVICES***

| **Glavno tehnično področje**  *Main technical area* | **Tehnično področje**  *Technical area* | | **Skupina proizvodov v okviru tehničnega področja**  *Product categories covered by the technical area* | **Omejitve**  *Limitations* |
| --- | --- | --- | --- | --- |
| Deli ali storitve  *Parts or services* |  | Osnovni material  *Raw materials* | Kovine, plastika, les, keramika  *Raw metals, plastic, wood, ceramic* |  |
|  | Komponente\*\*\*\*  *Components\*\*\*\** | Električne komponente, pritrdilni elementi, oblikovane surovine, strojno obdelane surovine in oblikovana plastika  *Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic* |  |
|  | Podsklopi\*\*\*\*  *Subassemblies\*\*\*\** | Elektronski podsklopi, mehanski podsklopi, izdelane na risbe in/ali navodila za delo  *Electronic subassemblies, mechanical subassemblies, made to drawings and/or work instructions* |  |
|  | Kalibracije  *Calibration services* | Storitve preverjanja/potrditve za merilne instrumente, orodja ali preskusne naprave  *Verification/confirmation services for measuring instruments, tools or test fixtures* |  |
|  | Distribucija  *Distribution services* | Distributerji, ki zagotavljajo skladiščenje in dostavo medicinskih pripomočkov, ne tisti, ki delujejo kot "pravni proizvajalec" za medicinske pripomočke  *Distributors providing storage and delivery of medical devices, not acting as a ‘legal manufacturer’ for medical devices* |  |
|  | Vzdrževanje\*\*\*\*  *Maintenance services\*\*\*\** | Električno ali mehansko popravilo, čiščenje in vzdrževanje objektov, čiščenje in ESD (elektrostatična razelektritev) testiranje delovne obleke  *Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD (electrostatic discharge) smocks* |  |
|  | Transport  *Transportation services* | Kopenski, morski in zračni prevoz, prevoz v splošnem  *Trucking, shipping, air transportation service in general* |  |
|  | Druge storitve\*\*\*\*  *Other services\*\*\*\** | Svetovalne storitve, povezane z medicinski pripomočki, storitve pakiranja itd.  *Consulting services related to medical devices, packaging services, etc.* |  |

\*\*\* Ko organizacija izvaja poslovne procese ali proizvodnjo delov, ki niso uvrščeni v končne izdelke (končani medicinski pripomoček je opredeljen kot pripomoček ali dodatna oprema kateremu koli medicinskemu pripomočku, primeren za uporabo ali sposoben delovanja, ne glede na to, ali je pakiran, označen ali steriliziran), se za obseg uporabi zgornjo tabelo. / *A finished medical device is defined as any device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized. Where the organization provides associated activities or manufacturing of parts which are not categorized as finished medical devices, the above table shall be used for scope.*

\*\*\*\*Pri akreditaciji za tehnična področja Komponente, Podsklopi, Vzdrževanje in Druge storitve, ko so ti Deli ali storitve jasno namenjeni podpori medicinskim pripomočkom (oglaševanje organizacije), mora certifikacijski organ imeti akreditacijo za ustrezna tehnična področja iz prvih šestih tabel v poglavju 7.4 te prijave. / *In the case of accreditation for the technical areas Components, Subassemblies, Maintenance services and Other services, when these parts or services are clearly intended to support medical devices (advertisement of the organization), the certification body must be accredited for the relevant technical areas from the first six tables in chapter 7.4 of this application.*

## Certificiranje sistemov vodenja varnosti živil (SIST EN ISO 22000) / *Certification of food safety management systems (SIST EN ISO 22000)*

Označite področja (kategorijo prehrambene verige in sektor), za katera želite pridobiti akreditacijo (ISO 22003-1, Priloga A). / *Indicate what areas (category and sector) the certification body wants to obtain accreditation for (categories according to ISO 22003-1 Annex A)*.

| **Grozd** / *Cluster* | **Kategorija** / *Category* | | **Podkategorija** / *Subcategory* | | **Primeri vključenih aktivnosti** / *Examples of included activities* |
| --- | --- | --- | --- | --- | --- |
| Primarna pridelava  *Primary production* | A | Živinoreja ali ravnanje z živalmi  *Farming or handling of animals* | AI | Reja živali za meso, mleko, jajca, med  *Farming of animals for meat / milk / eggs / honey* | Reja živali (razen rib in organizmov z akvakulture), ki se uporabljajo za pridelavo mesa, jajc, mleka in medu  *Raising animals (other than fish and aquaculture) used for meat production, egg production, milk production or honey production*  Gojenje, oskrba, ulov in lov (zakol ob ulovu)  *Growing, keeping, trapping and hunting (slaughtering at point of hunting)*  Začasno pakiranje brez spreminjanja ali predelave proizvoda  *Associated temporary packing without modification or processing of the product* |
| AII | Gojenje rib in morskih sadežev  *Farming of fish and seafood* | Gojenje rib in morskih sadežev, ki se uporabljajo za proizvodnjo mesa  *Raising fish and seafood used for meat production*  Gojenje, lov in ribolov (zakol ob ulovu)  *Growing, trapping and fishing (slaughtering at point of capture)*  Začasno pakiranje brez spreminjanja ali predelave proizvoda  *Associated temporary packing without modification or processing of the product* |
| B | Pridelava ali ravnanje z rastlinami  *Farming or handling of plants* | BI | Gojenje rastlin (razen žit in stročnic)  *Farming of plants (other than grains and pulses)* | Gojenje ali nabiranje rastlin (razen žit in stročnic): hortikulturni proizvodi (sadje, zelenjava, začimbe, gobe …) in hidrofiti za hrano  *Growing or harvesting of plants (other than grains and pulses): horticultural products (fruits, vegetables, spices, mushrooms, etc.) and hydrophytes for food*  Shranjevanje rastlin na kmetiji (razen žit in stročnic), vključno s hortikulturnimi proizvodi in hidrofiti za hrano  *On farm storage of plants (other than grains*  *and pulses), including horticultural*  *products and hydrophytes for food* |
| BII | Gojenje žit in stročnic  *Farming of grains and pulses* | Gojenje ali žetev žit in stročnic za hrano  *Growing or harvesting of grains and pulses for food*  Ravnanje z žiti in stročnicami  *Handling grains and pulses.*  Shranjevanje žit in stročnic za hrano na kmetiji  *On farm storage of grains and pulses for*  *food* |
| BIII | Predhodna obdelava rastlinskih proizvodov  *Pre-process handling of plant products* | Dejavnosti na pridelanih rastlinah, ki ne preoblikujejo proizvoda iz prvotne celotne oblike, vključno s hortikulturnimi proizvodi in hidrofiti za hrano. To vključuje čiščenje, pranje, izpiranje, prezračevanje, sortiranje, razvrščanje, obrezovanje, zbiranje, hlajenje, vodno hlajenje, voskanje, namakanje, prezračevanje, pripravo za skladiščenje ali predelavo, pakiranje, prepakiranje, odlaganje, skladiščenje in nakladanje.  *Activities on harvested plants that do not transform the product from original whole form, including horticultural products and hydrophytes for food. These include cleaning, washing, rinsing, fluming, sorting, grading, trimming, bundling, cooling, hydro-cooling, waxing, drenching, aeration, preparing for storage or processing, packing, repacking, staging, storing and loading.* |
| Predelava hrane za ljudi in živali  *Processing food for humans and animals* | C | Predelava živil, sestavin in hrane za hišne živali  *Food, ingredient and pet food processing* | C0 | Živali – Primarna obdelava  *Animal – Primary conversion* | Obdelava živalskih trupov za nadaljnjo predelavo, vključno z začasno namestitvijo, zakolom, evisceracijo, hlajenjem v razsutem stanju, zamrzovanjem razsutega tovora, skladiščenjem živali in drobovja divjadi, zamrzovanjem rib v razsutem stanju in skladiščenjem divjadi.  *Conversion of animal carcasses intended for further processing including lairage, slaughter, evisceration, bulk chilling, bulk freezing, bulk storage of animals and game gutting, bulk freezing of fish and storage of game* |
| CI | Predelava pokvarljivih živalskih proizvodov  *Processing of perishable animal products* | Predelava in pakiranje, vključno z ribami,  ribjimi proizvodi, morskimi sadeži, mesom, jajci in mlečnimi proizvodi, ki zahteva hlajenje ali zamrzovanje  *Processing and packaging including fish,*  *fish products, seafood, meat, eggs and dairy*  *requiring chilled or frozen temperature control*  Predelava hrane za hišne živali samo iz živalskih proizvodov  *Processing of pet food from animal products*  *only* |
| CII | Predelava pokvarljivih rastlinskih proizvodov  *Processing of perishable plant-based products* | Predelava in pakiranje, vključno s sadjem in svežimi sokovi, zelenjavo, žiti, oreščki, stročnicami, zamrznjenimi proizvodi na vodni osnovi, rastlinski nadomestki mesa in mlečnih proizvodov  *Processing and packaging including fruits and fresh juices, vegetables, grains, nuts, pulses, frozen water-based products, plant-based meat and dairy substitutes*  Predelava hrane za hišne živali samo iz rastlinskih proizvodov  *Processing pet food from plant products only* |
| CIII | Predelava pokvarljive živalske in rastlinske hrane (mešani proizvodi)  *Processing of perishable animal and plant products (mixed products)* | Predelava in pakiranje, vključno s pico, lazanjo, sendviči, cmoki in pripravljenimi jedmi. Vključuje kuhinje za catering izven lokacije.  Vključuje proizvode iz industrijskih kuhinj, ki niso namenjeni takojšnji potrošnji  *Processing and packaging including pizza, lasagne, sandwiches, dumplings and ready-to-eat meals.*  *Includes off-site catering kitchens.*  *Includes products of industrial kitchens not offered for immediate consumption*  Predelava pokvarljive hrane za hišne živali iz mešanih proizvodov  *Processing perishable pet food from mixed products* |
| CIV | Predelava proizvodov, stabilnih na sobni temperaturi  *Processing of ambient stable products* | Predelava in pakiranje proizvodov, shranjenih in prodanih pri sobni temperaturi, vključno s hrano v pločevinkah, piškoti, prigrizki, oljem, pitno vodo, pijačami, testeninami, moko, sladkorjem in soljo za živila  *Processing and packaging of products stored and sold at ambient temperature including canned foods, biscuits, snacks, oil, drinking water, beverages, pasta, flour, sugar and food-grade salt*  Predelava hrane za hišne živali, ki je stabilna pri sobni temperaturi  *Processing* *ambient stable pet food* |
| D | Predelava krme in živalske hrane  *Feed and animal food processing* | | | Predelava krmil, namenjenih živalim za proizvodnjo hrane in neživil, ki niso hišne živali, npr. moka iz žita, oljnic, stranski proizvodi pri proizvodnji hrane  *Processing feed material intended for food and non-food producing animals not kept in households, e.g. meal from grain, oilseeds, by-products of food production*  Predelava krmnih mešanic z ali brez dodatkov, namenjenih živalim za proizvodnjo hrane, npr. premiksi, medicirana krma, krmne mešanice  *Processing feed mixtures, with or without additives, intended for food-producing animals, e.g. premixes, medicated feed, compound feeds* |
| Oskrba s hrano in pijačo/postrežba hrane  *Catering/food service* | E | Oskrba s hrano in pijačo/postrežba hrane  *Catering/food service* | | | Aktivnosti priprave hrane, kot so kuhanje, mešanje in združevanje, priprava sestavin in proizvodov za neposredno potrošnjo na kraju samem ali za s seboj.  Primeri vključujejo restavracije, hotele, tovornjake s hrano, ustanove, delovna mesta (šolska ali tovarniška menza), vključno z maloprodajo s pripravo na kraju samem (npr. piščanec na žaru). Vključuje pogrevanje hrane, catering za dogodke, kavarne in bare.  *Open exposed food activities such as cooking, mixing and blending, preparation of components and products for on-site direct consumer consumption or take away.*  *Examples include restaurants, hotels, food trucks, institutions, workplaces (school or factory cafeteria), including retail with on-site preparation (e.g. rotisserie chicken). Includes reheating of food, event catering, coffee shops and pubs* |
| Prodaja, transport in skladiščenje  *Retail, transport and storage* | F | Trgovanje, trgovina na drobno in e-poslovanje *Trading, retail and e-commerce* | FI | Prodaja na drobno / prodaja na debelo  *Retail / wholesale* | Skladiščenje in dobava gotovih proizvodov strankam in potrošnikom (maloprodaja, trgovine, veletrgovci). Vključuje manjše dejavnosti predelave, npr. rezanje, porcioniranje, pogrevanje.  *Storage and provision of finished products to customers and consumers (retail outlets, shops, wholesalers). Includes minor processing activities, e.g. slicing, portioning, reheating* |
| FII | Posredovanje / trgovanje *Brokering / trading* | Nakup in prodaja proizvodov, ki vstopijo v prehranjevalno verigo, za svoj račun brez fizičnega ravnanja ali kot zastopnik za druge *Buying and selling products on its own account without physical handling or as an agent for others of any item that enters the food chain* |
| G | Transport in skladiščenje  *Transport and storage services* |  |  | Skladiščenje in prevoz pokvarljive hrane in krme, kjer je treba vzdrževati neoporečno temperaturo  *Storage facilities and distribution vehicles for perishable food and feed where temperature integrity shall be maintained*  Skladiščenje in prevoz hrane in krme, stabilne pri sobni temperaturi  *Storage facilities and distribution vehicles for ambient stable food and feed*  Ponovno označevanje/prepakiranje, razen odprtih izpostavljenih materialov proizvoda  *Relabelling/repackaging excluding open exposed product materials*  Skladiščenje in prevoz embalažnega materiala za živila  *Storage facilities and distribution vehicles for food packaging material* |
| Pomožne storitve  *Auxiliary services* | H | Storitve  *Services* | | | Zagotavljanje storitev v zvezi z varno proizvodnjo hrane in krme, vključno z oskrbo z vodo, zatiranjem škodljivcev, čiščenjem, odstranjevanjem odpadkov  *Services provisioned related to the safe production of food and feed, including water supply, pest control, cleaning services, waste disposal* |
| Embalažni material  *Packaging material* | I | Proizvodnja embalažnega materiala  *Production of packaging materials* | | | Proizvodnja embalaže v stiku z živili, krmo in hrano za živali.  Lahko vključuje embalažo, proizvedeno na kraju samem za uporabo pri predelavi *Production of packaging material in contact with food, feed and animal food*  *May include packaging produced on-site for use in processing* |
| Pomožna oprema  *Auxiliary equipment* | J | Oprema  *Equipment* | | | Oprema za predelavo hrane, krme ali embalaže, prodajni avtomati, kuhinjska oprema, predelovalne posode, filtri, higiensko oblikovanje opreme in prostorov  *Equipment for food, feed or packaging processing, vending machines, kitchen equipment, processing utensils, filters, hygienic design of equipment and facilities* |
| Bio/kemične snovi *Bio/chemical* | K | Kemične in biokemične snovi  *Chemicals and biochemicals* | | | Proizvodnja pripomočkov za predelavo živil in krme, dodatki (npr. arome, vitamini), plini in minerali  *Production of food and feed processing aids, additives (e.g. flavourings, vitamins), gases and minerals*  Proizvodnja biokultur in encimov  *Production of bio-cultures and enzymes* |

## Certificiranje sistemov upravljanja z energijo (ISO 50001) / *Certification of energy management systems (ISO 50001)*

Označite področja, za katera želite pridobiti akreditacijo. / *Indicate what areas the certification body wants to obtain accreditation for.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Tehnično področje** / *Technical area* | | **Opis** / *Description* | **Primeri** / *Examples* |
|  | Industrija – lahka do srednja  *Industry – light to medium* | Proizvodni objekti, ki proizvajajo polizdelke ali izdelke za končno uporabo  *Manufacturing facilities producing consumer intermediates or end user-oriented products* | • oblačila / *clothing*  • zabavna elektronika / *consumer electronics*  • gospodinjski aparati, pohištvo / *home appliances, furniture*  • plastika / *plastics*  • izdelava / *fabrication*  • specialne kemikalije / *speciality chemicals*  • predelava hrane / *food processing*  • čiščenje vode in odpadnih voda / *water and wastewater treatment* |
|  | Industrija – težka  *Industry – heavy* | Proizvodni objekti, ki zahtevajo visoko kapitalizacijo in kjer se porabljajo velike količine surovine in energije  *Manufacturing facilities requiring high capitalization and consuming large quantities of raw materials and energy* | • kemikalije / *chemicals*  • jeklo in kovine / *steel and metals*  • rafiniranje nafte / *oil refining*  • ladjedelništvo / *ship-building*  • celuloza in papirnice / *pulp and paper mills*  • industrijski stroji / *industrial machinery*  • polprevodniki / *semiconductors*  • cement in keramika / *cement and ceramic* |
|  | Zgradbe  *Buildings* | Objekti s standardnimi poslovnimi procesi  *Facilities with standard commercial building practices* | • pisarne / *offices*  • nastanitev / *lodging*  • maloprodaja / *retail*  • skladišče / *warehouse* |
|  | Gradbeni kompleksi  *Building complexes* | Objekti z operacijami, ki zahtevajo posebno strokovno znanje zaradi kompleksnosti virov energije in uporabe  *Facilities with operations requiring specific expertise due to the complexity of energy sources and uses* | • zdravstvene ustanove / *health care facilities*  • laboratoriji / *laboratories*  • podatkovni centri / *data centres*  • univerzitetna središča / *educational campuses*  • vojaški in vladni kompleksi s skupno oskrbo z energijo (daljinsko ogrevanje in hlajenje) / *military and government campuses with integrated energy supply (district heating and cooling)*  • občine / *municipalities* |
|  | Transport  *Transport* | Sistemi ali sredstva za prevoz oseb ali blaga / tovora  *Systems or means for transporting people or goods/cargo* | • potniške storitve (vozila, vlak, ladja, letala) / *passenger services (vehicles, train, ship, airplanes)*  • občine / *municipalities*  • transportne storitve / *trucking services*  • flote / *fleets*  • železniško poslovanje / *rail operations*  • križarjenje / *cruise lines*  • letalske družbe, letalski tovorni promet / *airlines, airfreight* |
|  | Rudarstvo  *Mining* | Dnevni kop, podzemni kop in tekočinska ekstrakcija surovin ter prevoz  *Open cast, underground and fluid extraction of raw materials and transport* | • ločevanje mineralov / *mineral separation*  • hidro metalurgija / *hydrometallurgy*  • taljenje in rafiniranje / *smelting and refining*  • vrtanje naftnih in plinskih vrtin / *oil and gas drilling operations*  • plinovodi in naftovodi / *gas- and oil pipelines* |
|  | Kmetijstvo  *Agriculture* | Živinoreja, pridelava semen ali rastlin  *Livestock, seed or crops products* | • kmetovanje / *farming*  • proizvodnja semen / *seed production*  • vlečenje materialov / *hauling of materials*  • živinoreja / *animal production* |
|  | Oskrba z energijo  *Energy supply* | Proizvodnja energije (jedrska, CHP, elektrika, obnovljivi viri itd.) in prevoz (za prenos in distribucijo)  *Energy generation (nuclear, CHP, electricity, renewable, etc.) and transport (transmission and distribution)* | • proizvodnja električne energije (premog, nafta, zemeljski plin, obnovljivi viri, CHP, IGCC itd.) / *power generation (coal, oil, natural gas, renewable, CHP, IGCC, etc.)* |

## Certificiranje sistemov vodenja kakovosti na področju zdravstvene dejavnosti (po SIST EN 15224) / *Certification of quality management systems in healthcare services (SIST EN 15224)*

Označite področja, za katera želite pridobiti akreditacijo. / *Indicate what areas the certification body wants to obtain accreditation for.*

|  |  |  |
| --- | --- | --- |
| **Področje aktivnosti** / *Field of activity* | | **Omejitve** / *Limitations* |
|  | Osnovna zdravstvena dejavnost / *Primary health care activity* |  |
|  | Dejavnost specialističnih ambulant / *Activities of specialist outpatient clinics* |  |
|  | Bolnišnična dejavnost / *Hospital activity* |  |
|  | Dejavnost klinik in kliničnih oddelkov / *Activities of clinics and clinical departments* |  |
|  | Dejavnost javnega zdravstva in z njim povezane dejavnosti / *Public health and related activities* |  |
|  | Nujna medicinska pomoč / *Emergency medical treatment* |  |
|  | Lekarne / *Pharmacies* |  |
|  | Zdravstvena dejavnost v okviru socialno varstvenega zavoda / *Healthcare activities within the framework of the social welfare institution* |  |

## Certificiranje trajnostnega gospodarjenja z gozdovi po Balkanski shemi PEFC BS 01:2021 / *Certification of sustainable forest management according to Balkan Forest Certification System PEFC BS 01:2021*

Označite področja, za katera želite pridobiti akreditacijo. / *Indicate what areas the certification body wants to obtain accreditation for.*

| Dodatne zahteve za usposobljenost / *Additional requirements for competence*: PEFC BS 01:2021, PEFC BS 04:2021, PEFC BS 05:2023 | | | | |
| --- | --- | --- | --- | --- |
| Certificiranje v skladu s shemo / *Certification in accordance with scheme*: **Trajnostno gospodarjenje z gozdovi po PEFC BS 01:2021 skladno s shemo…..** (oznaka dokumenta sheme) **/ *Sustainable forest management based on PEFC BS 01: 2021 in accordance with the scheme****…(identification of scheme document/its parts)* | | | | |
| Tip obsega: **fiksni / fleksibilni (opis)\*** / *Type of scope:* ***fixed / flexible (description)\**** | | | | |
|  | **Raven certificiranja**  **Level of certification** | **Oznaka standarda** ali normativnega dokumenta  (v celoti ali delno)  **Reference** to standard or normative document (entirely or partly) | | **Naslov standarda** ali normativnega dokumenta v celoti oz. delno (npr. poglavje, del, točka)  **Title** of standard or normative document entirely or partly (e.g. part, chapter, article) |
|  | Individualna certifikacija / *Individual certification* |  | Slovenska shema za certifikacijo gozdov / *Slovenian Forest Certification Scheme*  PEFC SLO 03:2021 | Merila in kazalniki za trajnostno gospodarjenje z gozdovi / *Criteria and indicators for sustainable forest management* |
|  | Severno Makedonska shema za certifikacijo gozdov / *North Macedonian Forest Certification Scheme*  PEFC MK 03:2021 | *PEFC National Standard for Sustainable Forest management in North Macedonia* |
|  | Bosansko-Hercegovska shema za certifikacijo gozdov / *Forest Certification Scheme of Bosnia and Herzegovina*  PEFC B&H 03:2021 | *PEFC National Standard for Sustainable Forest management in Bosnia and Herzegovina* |
|  | Skupinska certifikacija / *Group certification* |  | Slovenska shema za certifikacijo gozdov / *Slovenian Forest Certification Scheme*  PEFC SLO 03:2021  PEFC BS 06:2021 | Merila in kazalniki za trajnostno gospodarjenje z gozdovi / *Criteria and indicators for sustainable forest management*  Pravila in postopki za skupinsko certifikacijo / *Group Forest Management Rules and Procedures* |
|  | Severno Makedonska shema za certifikacijo gozdov / *North Macedonian Forest Certification Scheme*  PEFC MK 03:2021  PEFC BS 06:2021 | *PEFC National Standard for Sustainable Forest management in North Macedonia*  Pravila in postopki za skupinsko certifikacijo / *Group Forest Management Rules and Procedures* |
|  | Bosansko-Hercegovska shema za certifikacijo gozdov / *Forest Certification Scheme of Bosnia and Herzegovina*  PEFC B&H 03:2021  PEFC BS 06:2021 | *PEFC National Standard for Sustainable Forest management in Bosnia and Herzegovina*  Pravila in postopki za skupinsko certifikacijo / *Group Forest Management Rules and Procedures* |

## Certificiranje sistemov upravljanja premoženja po ISO 55001 / *Certification of asset management systems according to ISO 55001*

Označite področja, za katera želite pridobiti akreditacijo. / *Indicate what areas the certification body wants to obtain accreditation for*:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Kategorija  *Category* | | Podkategorija  *Subcategory* | | IAF kode  *IAF code* |
|  | Fizično premoženje / *Physical assets* |  | Javna infrastruktura  *Public infrastructure* | 28 |
|  | Infrastrukturna omrežja  *Infrastructure networks* | 25, 26, 27  31 (NACE 61) |
|  | Objekti  *Facilities* | 29, 30, 31 (NACE 52), 34, 35, 36, 37, 38, 39 (brez NACE 38, 39, 93.2) |
|  | Prevozna sredstva  *Means of transport* | 1 (NACE 03.1), 28, 31 (NACE 49, 50, 51, 53) |
|  | Premoženje v industriji  *Assets in industry* | 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 |
|  | Finančno premoženje / *Financial assets* |  | Finančna sredstva, nepremičnine  *Financial resources, real estate* | 32 |
|  | Biološko premoženje / *Biological assets* |  | Rastline  *Plants* | 1 (NACE 01.1 – 3, 01.5, 02, 91.4) |
|  | Živali  *Animals* | 1 (NACE 01.4, 03, 91.4) |
|  | Intelektualno premoženje / *Intellectual property* |  | Patenti, IT, blagovne znamke …  *Patents, IT, trademarks …* | 33 |

## Certificiranje sistemov vodenja po drugih shemah (navesti shemo) / *Certification of management systems according to other schemes (name the scheme):*

|  |  |
| --- | --- |
|  |  |
|  |  |

Opišite področja certificiranja, za katera želite pridobiti akreditacijo / *Please describe the certification areas for which you are seeking accreditation.*

|  |
| --- |
|  |

# INFORMACIJA O NOSILCIH CERTIFIKATOV / *Information on* *valid certificates*

## Ali obstaja spisek podjetij, nosilcev certifikatov certifikacijskega organa? / *Is there a list of certified companies?*

DA / YES  NE / NO

Kako je ta spisek dostopen? / *How is this list accessible?*

na voljo je na internetni strani / *available on the Internet*:

|  |
| --- |
|  |

na voljo je pri certifikacijskem organu (prosimo, da priložite seznam imetnikov certifikatov) / *available at certification body (please attach a list of certified persons)*

# ŽELIMO, DA SA IZVEDE PREDOCENJEVANJE / *We want SA to perform pre-assessment*

DA / YES  NE / NO

**ŽELIMO, DA SA OCENJEVANJE ZA ŠIRITEV OBSEGA AKREDITACIJE IZVEDE IZVEN TERMINA REDNEGA NADZORA KOT IZREDNO OCENJEVANJE (to možnost lahko izkoristite le enkrat v akreditacijskem ciklu) / *We want SA to perform assessment for extension of accreditation scope outside the regular surveillance period as an extraordinary assessment (this option can only be used once in an accreditation cycle)***

DA / YES  NE / NO

1. **IZJAVA / Statement**

**Izjavljamo, da smo seznanjeni z naslednjimi pogoji za izvedbo postopka akreditiranja in jih sprejemamo / We hereby declare that we are aware of and accepting the following conditions for the performance of accreditation procedure:**

* vzpostavljen in delujoč sistem vodenja kakovosti, ki omogoča izpolnjevanje vseh zahtev standarda SIST EN ISO/IEC 17021-1 / implemented and operational quality management system which fulfils all requirements of the standard SIST EN ISO/IEC 17021-1;
* sistem vodenja kakovosti dokumentiran v obsegu, ki ga zahteva standard SIST EN ISO/IEC 17021-1 / management system documented as required by the standard SIST EN ISO/IEC 17021-1;
* izvedena najmanj ena notranja presoja v celotnem obsegu in najmanj en vodstveni pregled, upoštevajoč zahteve standarda SIST EN ISO/IEC 17021-1 / at least one complete internal audit and at least one management review respecting all requirements of the standard SIST EN ISO/IEC 17021-1 carried out;
* aktivno izvajanje postopkov certificiranja v celotnem obsegu, ki je naveden v tej prijavi / *active performance of certifications specified in the applied scope of accreditation*;
* izpolnjevanje zahtev za akreditacijo in obveznosti do SA v zvezi z akreditacijo / fulfilling the requirements for accreditation and other obligations to SA relating to accreditation.

**Poleg tega izjavljamo, da smo seznanjeni s splošnimi pogoji za izvedbo postopka akreditiranja, vezanimi na informacije in dostop do osebnih podatkov, ki so dostopni na spletni strani SA:** [**https://www.slo-akreditacija.si/o-nas/o-slovenski-akreditaciji/politika-varstva-osebnih-podatkov/**](https://www.slo-akreditacija.si/o-nas/o-slovenski-akreditaciji/politika-varstva-osebnih-podatkov/)**, in jih sprejemamo. / We in addition hereby declare that we are aware of and accepting the conditions for the performance of accreditation procedure regarding information and access to personal data, which are available at SA website:** [***https://www.slo-akreditacija.si/about-us/about-sa/personal-data-protection-policy-in-carrying-out-accreditation-procedures-2/?lang=en***](https://www.slo-akreditacija.si/about-us/about-sa/personal-data-protection-policy-in-carrying-out-accreditation-procedures-2/?lang=en)**.**

# PRILOGE / Attachments

**Ob prvi prijavi za akreditacijo** priložiti vsa navedena dokazila, v ostalih primerih pa le tista, ki so specifična za prijavljeno širitev obsega: / *When first applying for accreditation attach all listed evidence, and in other cases only those that are specific to the applied scope for extension*:

Potrdilo o nekaznovanosti pravne osebe oz. Potrdilo o nekaznovanosti fizične osebe, kadar gre za samostojnega podjetnika (za pridobitev se obrnite na Ministrstvo za pravosodje RS) (opomba: dokazila ne priložite, če spadate med državne organe) / *Certificate of non-conviction for legal person or – in the case of sole trader – certificate of impunity of natural person* (contact the Ministry of Justice of the Republic of Slovenia) *(note: no certificate needed if you belong to a state authority)*

Izpisek iz evidence o pravnomočnih odločbah o prekrških, iz katerega izhaja, da niste bili pravnomočno spoznani za odgovorno za storitev prekrška, ki je v povezavi s področji dejavnosti, prijavljenimi za akreditacijo (za pridobitev se obrnite na Ministrstvo za pravosodje RS) / *Extract from the Criminal Record to certify that the client has not been finally held liable for committing an offence related to the fields of activities applied for accreditation* (contact the Ministry of Justice of the Republic of Slovenia)

Organizacijski diagram / Organizational chart

Izpis dejavnosti iz sodnega registra / *Extract of activities from judicial record*

Podatki odgovornega osebja certifikacijskega organa (Priloga 1 tega dokumenta) / *Information regarding responsible personnel of certification body (Annex 1 of this document)*

Seznam presojevalcev z informacijo o področju (EA in NACE področja), ki ga posameznik pokriva, in o kategorizaciji / A list of auditors with information about the area (EA and NACE codes), which covers the individual, and on the categorization in the field of certification

Seznam nosilcev certifikatov / *A list of certified companies*

|  |  |  |
| --- | --- | --- |
| , |  |  |
| Kraj, datum  *Place, date* |  | Ime in podpis odgovorne osebe  *Name and signature of responsible person* |

Žig

*Stamp*

PRILOGA / *ANNEX* 1: Podatki odgovornega osebja certifikacijskega organa (po posamezni shemi certificiranja) / *Information regarding responsible personnel of certification body (for each certification scheme)*

|  |  |
| --- | --- |
| **Vodja certificiranja /** *Head of Certification*  (Ime in priimek / *Name and Surname*) |  |
| Datum in kraj rojstva / *Date and place of birth* |  |
| Izobrazba / Education |  |
| Delovne izkušnje (leta) / Working experience (years) |  |
| Položaj, funkcija v organizaciji / Position, function in organization |  |
| Izkušnje na področju certificiranja (leta) / Experience in the field of certification (years) |  |

|  |  |
| --- | --- |
| **Namestnik vodje /** *Deputy Head*  (Ime in priimek / *Name and Surname*) |  |
| Datum in kraj rojstva / *Date and place of birth* |  |
| Izobrazba / Education |  |
| Delovne izkušnje (leta) / Working experience (years) |  |
| Položaj, funkcija v organizaciji / Position, function in organization |  |
| Izkušnje na področju certificiranja (leta) / Experience in the field of certification (years) |  |