CERTIFIKACIJSKA SHEMA – Modul B: EU-pregled tipa
CERTIFICATION SCHEME – Module B: EU Type-examination

1. ZAHTEVE IN VODILA / *CRITERIA AND GUIDELINES*

1.1. Zahteve za certificiranje / *Certification criteria*

Uredba (ES) 2016/425 evropskega parlamenta in sveta **o osebni varovalni opremi** (*v nadaljnjem* Uredba (EU) 2016/425)
*Regulation (EU) 2016/425 of the European parliament and of the council **on personal protective equipment** (hereinafter referred to as Regulation (EU) 2016/425)*

1.2. Zahteve za postopek ugotavljanja skladnosti
Requirements for a conformity assessment procedure

Priloga V, Modul B, EU-pregled tipa
Annex V, Module B, EU type-examination

1.3. Zahteve za izdelek / *Requirements for a product*

Priloga II: Bistvene zdravstvene in varnostne zahteve
Annex II: Essential Health and Safety Requirements

Priloga III: Tehnična dokumentacija za osebno varovalno opremo (*v nadaljevanju* OVO)
Annex III: Technical documentation for Protective Personal Equipment (hereinafter PPE)

1.4. Harmonizirani standard za sistem vodenja kakovosti
Harmonised standard for quality management system

ISO 9001:2015 Sistemi vodenja kakovosti – Zahteve
ISO 9001:2015 Quality management systems – Requirements

1.5. Harmonizirani standardi oziroma normativni dokumenti za izdelek
Harmonised standard and normative documents for product

EN 149:2001+A1:2009, Oprema za varovanje dihal – polobrazne maske za zaščito pred delci – zahteve, preskušanje, označevanje
EN 149:2001+A1:2009, Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking

ISO 16972:2020, Oprema za varovanje dihal - Slovar in grafični simboli
ISO 16972:2020, Respiratory protective devices - Vocabulary and graphical symbols

EN 134:1998, Oprema za varovanje dihal - Poimenovanje sestavnih delov
EN 134:1998 Respiratory protective devices - Nomenclature of components

EN 143:2000+A1:2006, Oprema za varovanje dihal - Filtri za zaščito pred delci - Zahteve, preskušanje, označevanje
EN 143:2000+A1:2006, Respiratory protective devices - Particle filters - Requirements, testing, marking

EN 13274-7:2019, Oprema za varovanje dihal - Metode preskušanja - Ugotavljanje penetracije delcev v filter
EN 13274-7:2019, Respiratory protective devices - Methods of test - Determination of particle filter penetration

ISO 6941:2003, Tekstilije - Gorljivost - Meritve razširjanja plamena navpično nameščenih preskušancev
ISO 6941:2003, Textile fabrics - Burning behaviour - Measurement of flame spread properties of vertically oriented specimens

2. NALOGE PROIZVAJALCA IN PRIGLAŠENEGA ORGANA
THE MANUFACTURER AND NOTIFIED BODY SHALL

2.1. Naloge proizvajalca / *The manufacturer shall*

- Proizvajalec vloži zahtevek za EU-pregled tipa pri priglašenem organu, ki ga izbere sam.
- Proizvajalec obvesti priglašeni organ, ki hrani tehnično dokumentacijo v zvezi s certifikatom o EU-pregledu tipa, o kakršnih koli spremembah odobrenega tipa in o kakršnih koli spremembah tehnične dokumentacije, ki bi lahko vplivale na skladnost OVO z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami ali s pogoji veljavnosti certifikata. Take spremembe zahtevajo dodatno odobritev v obliki dodatka k izvirnemu certifikatu o EU-pregledu tipa.
- Proizvajalec zagotovi, da OVO še naprej izpolnjuje veljavne bistvene zdravstvene in varnostne zahteve glede na najnovejše stanje na področju tehnološkega razvoja.
- Proizvajalec priglašeni organ zaprosi za pregled certifikata o EU-pregledu tipa v enem od naslednjih primerov:
    - v primeru spremembe odobrenega tipa iz točke 7.2, Priloge V, Uredbe (ES) 2016/425,
    - v primeru spremembe stanja na področju tehnološkega razvoja iz točke 7.3, Priloge V, Uredbe (ES) 2016/425,
    - najpozneje pred datumom izteka veljavnosti certifikata. Da bi lahko priglašeni organ izpolnil svoje naloge, proizvajalec predloži vlogo nič prej kot dvanajst mesecev in nič pozneje kot šest mesecev pred datumom izteka veljavnosti certifikata o EU-pregledu tipa.
- Kadar pogoja iz točk (a) in (b) točke 7.4, Priloge V, Uredbe (ES) 2016/425, nista izpolnjena, se uporabi poenostavljeni postopek pregleda. Proizvajalec priglašenemu organu predloži naslednje:
    - svoje ime in naslov ter podatke za identifikacijo zadevnega certifikata o EU-pregledu tipa,
    - certifikat iz točke 7.2, Priloge V, Uredbe (ES) 2016/425, da odobreni tip, vključno z materiali, pod-komponentami ali podsestavi, pa tudi uporabljeni ustrezni harmonizirani standardi ali tehnične specifikacije niso bili spremenjeni,
    - certifikat, da ni bilo nobene spremembe stanja na področju tehnološkega razvoja iz točke 7.3, Priloge V, Uredbe (ES) 2016/425,
    - izvode skic in fotografij sedanjih proizvodov, oznake proizvodov in informacije, ki jih zagotovi proizvajalec, kadar vse to priglašenemu organu še ni bilo predloženo,
    - za proizvode iz kategorije III, če priglašeni organ še nima teh informacij, informacije o rezultatih nadzorovanih preskusov proizvodov v naključno

izbranih časovnih presledkih, izvedenih v skladu s Prilogo VII, ali o rezultatih pregledov svojega sistema kakovosti, opravljenih v skladu s Prilogo VIII.

- Proizvajalec še deset let po tem, ko je bila OVO dana na trg, omogoča nacionalnim organom dostop do izvoda certifikata o EU-pregledu tipa, njegovih prilog in dodatkov, vključno s tehnično dokumentacijo,
- Proizvajalec izpolnjuje splošne zahteve certifikacijskega organa, objavljene na spletni strani certifikacijskega organa.

- *The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.*
- *The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.*
- *The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in the light of the state of the art.*
- *The manufacturer shall ask the notified body to review the EU type-examination certificate either:*
    - *in the case of a modification to the approved type referred to in point 7.2 of Annex V, of the Regulation (EU) 2016/425,*
    - *in the case of a change in the state of the art referred to in point 7.3, Annex V, Regulation (EU) 2016/425,*
    - *at the latest, before the date of expiry of the certificate. In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.*
- *Where the conditions referred to in points (a) and (b) of point 7.4, Annex V, Regulation (EU) 2016/425 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:*
    - *his name and address and data identifying the EU type-examination certificate concerned,*
    - *confirmation that there has been no modification to the approved type as referred to in point 7.2, Annex V, Regulation (EU) 2016/425, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or other technical specifications applied,*
    - *confirmation that there has been no change in the state of the art as referred to in point 7.3, Annex V, Regulation (EU) 2016/425,*
    - *where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer,*
    - *for category III products, where not already available to the notified body, information on the results of the supervised product checks at random intervals carried out in accordance with Annex VII of the Regulation (EU) 2016/425, or on the results of audits of his quality system carried out in accordance with Annex VIII of the Regulation (EU) 2016/425.*
- *The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the PPE has been placed on the market,*

- *The manufacturer complies with the general requirements of the certification body, as published on the certification body's website.*

2.2. Naloge pooblaščenega predstavnika (če obstaja)
The authorised representative shall (if it exists)

- Obveznosti proizvajalca lahko v njegovem imenu in na njegovo odgovornost izpolni pooblaščeni zastopnik, če so navedene v pooblastilu, a v vsakem primeru mora pooblaščeni predstavnik izpolniti obveznosti proizvajalca iz točke 2, Priloge VII, Uredbe (ES) 2016/425.
- *The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate, but in any case, the authorised representative shall fulfil the manufacturer's obligations set out in point 2, Annex VII, Regulation (EU) 2016/425.*

2.3. Naloge priglašenega organa / *Notified body shall*

- Pregleda tehnično dokumentacijo, da oceni ustreznost tehničnega načrta osebne varovalne opreme. Pri takem pregledu mu ni treba upoštevati točke (j) Priloge III Uredbe (ES) 2016/425.
- Za OVO, proizvedeno v serijah, pri čemer je vsak kos prilagojen posameznemu uporabniku, pregleda opis ukrepov, da oceni njihovo ustreznost.
- Za OVO, proizvedeno kot samostojna enota, namenjena posameznemu uporabniku, pregleda navodila za izdelavo takšne OVO na podlagi odobrenega osnovnega modela, da oceni njihovo ustreznost.
- Preveri, ali je bil vzorec izdelan v skladu s tehnično dokumentacijo, ter določi elemente, ki so bili načrtovani v skladu z veljavnimi določbami ustreznih harmoniziranih standardov, in elemente, ki so bili načrtovani v skladu z drugimi ustreznimi tehničnimi specifikacijami.
- Izvede ali naroči ustrezne preglede in preskuse, s katerimi preveri, ali je proizvajalec, če se je odločil za uporabo rešitev iz ustreznih harmoniziranih standardov, te pravilno upošteval.
- Izvede ali naroči ustrezne preglede in preskuse, da bi, če rešitve iz ustreznih harmoniziranih standardov niso bile uporabljene, preveril, ali rešitve, ki jih je sprejel proizvajalec, vključno s tistimi iz drugih uporabljenih tehničnih specifikacij, izpolnjujejo ustrezne bistvene zdravstvene in varnostne zahteve in ali so bile uporabljene pravilno.
- Priglašeni organ pripravi poročilo o oceni, ki navaja ukrepe, sprejete v skladu s točko 4, Priloge V, Uredbe (ES) 2016/425, in njihove rezultate. Brez poseganja v obveznosti do priglasitvenih organov lahko priglašeni organ objavi vsebino navedenega poročila v celoti ali delno le, če se proizvajalec strinja.
- Kadar tip izpolnjuje veljavne bistvene zdravstvene in varnostne zahteve, priglašeni organ proizvajalcu izda certifikat o EU-pregledu tipa. Novo izdani certifikat in, kjer je to ustrezno, podaljšani certifikat veljata največ pet let.
- Če tip ne izpolnjuje veljavnih bistvenih zdravstvenih in varnostnih zahtev, priglašeni organ zavrne izdajo certifikata o EU-pregledu tipa in ustrezno obvesti vložnika s podrobno utemeljitvijo zavrnitve.
- Priglašeni organ spremlja kakršne koli spremembe splošno sprejetih najnovejših tehničnih dosežkov, ki kažejo, da odobreni tip ne izpolnjuje več veljavnih bistvenih zdravstvenih in varnostnih zahtev, ter določi, ali take spremembe zahtevajo nadaljnje preiskave. V tem primeru priglašeni organ ustrezno obvesti proizvajalca.

- Priglašeni organ pregleda tip osebne varovalne opreme in, kadar je potrebno glede na opravljene spremembe, izvede ustrezne preskuse za zagotovitev, da odobreni tip še naprej izpolnjuje veljavne bistvene zdravstvene in varnostne zahteve. Če priglašeni organ ugotovi, da odobreni tip še naprej izpolnjuje veljavne zdravstvene in varnostne zahteve, certifikat o EU-pregledu tipa podaljša. Priglašeni organ zagotovi, da je postopek pregleda opravljen pred datumom izteka veljavnosti certifikata o EU-pregledu tipa.
- Če priglašeni organ ugotovi, da je prišlo do spremembe stanja na področju tehnološkega razvoja iz točke 7.3, Priloge V, Uredbe (ES) 2016/425, se uporabi postopek iz točke 7.5, Priloge V, Uredbe (ES) 2016/425.
- Če po pregledu priglašeni organ ugotovi, da certifikat o EU-pregledu tipa ni več veljaven, ta organ certifikat umakne, proizvajalec pa preneha dajati na trg zadevno osebno varovalno opremo.
- Vsak priglašeni organ obvesti svoje priglasitvene organe o certifikatih o EU-pregledu tipa in/ali katerih koli njihovih dodatkih, ki jih je izdal ali umaknil, ter redno ali na zahtevo da na voljo priglasitvenim organom seznam zavrnjenih, začasno preklicanih ali drugače omejenih takih certifikatov in/ali kakršnih koli dodatkov.
- Vsak priglašeni organ obvesti druge priglašene organe o zavrnjenih, umaknjenih, začasno preklicanih ali drugače omejenih certifikatih o EU-pregledu tipa in/ali kakršnih koli dodatkih ter jih na zahtevo obvesti o izdanih takih certifikatih in/ali dodatkih.
- Komisija, države članice in drugi priglašeni organi lahko na zahtevo dobijo izvod certifikatov o EU-pregledu tipa in/ali njihovih dodatkov. Komisija in države članice lahko na utemeljeno zahtevo dobijo izvod tehnične dokumentacije in rezultatov pregledov, ki jih je izvedel priglašeni organ.
- Priglašeni organ hrani izvod certifikata o EU-pregledu tipa, njegovih prilog in dodatkov ter tehnične dokumentacije, vključno z dokumentacijo, ki jo je predložil proizvajalec, še pet let po izteku veljavnosti navedenega certifikata.

- *Examine the technical documentation to assess the adequacy of the technical design of the PPE. In conducting such an examination, point (j) of Annex III of the Regulation (EU) 2016/425 need not be taken into account.*
- *For PPE produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy.*
- *For PPE produced as a single unit to fit an individual user, examine the instructions for manufacturing such PPE on the basis of the approved basic model to assess their adequacy.*
- *Verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed in accordance with other technical specifications.*
- *Carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly.*
- *Carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.*
- *The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4, Annex V, Regulation (EU) 2016/425 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying*

authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

- *Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer. The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.*
- *Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.*
- *The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.*
- *The notified body shall examine the PPE type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.*
- *If the notified body finds that a change in the state of the art referred to in point 7.3, Annex V, Regulation (EU) 2016/425, has occurred, the procedure set out in point 7.5, Annex V, Regulation (EU) 2016/425, Regulation (EU) 2016/425 shall apply.*
- *If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.*
- *Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.*
- *Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.*
- *The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type- examination certificates and/or additions thereto. On a reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.*
- *The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.*

3. VRSTE POSTOPKOV / *TYPES OF PROCEDURES*

EU-pregled tipa

EU-pregled tipa je tisti del postopka ugotavljanja skladnosti, pri katerem priglašeni organ pregleda tehnično načrtovanje OVO ter preveri in potrdi, da tehnično načrtovanje OVO izpolnjuje zahteve iz te uredbe, ki veljajo zanjo.

EU-pregled tipa se izvaja z oceno ustreznosti tehničnega načrtovanja OVO s pregledom tehnične dokumentacije in s pregledom vzorca, reprezentativnega za predvideno proizvodnjo celotne OVO (tip proizvodnje).

Kadar tip izpolnjuje veljavne bistvene zdravstvene in varnostne zahteve, priglašeni organ proizvajalcu izda certifikat o EU-pregledu tipa.

EU type-examination

EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the requirements of this Regulation that apply to it. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation, plus examination of a specimen, representative of the production envisaged, of the complete PPE (production type).

Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.

Revizija obstoječega certifikata o EU-pregleda tipa

Priglašeni organ spremlja kakršne koli spremembe splošno sprejetih najnovejših tehničnih dosežkov, ki kažejo, da odobreni tip ne izpolnjuje več veljavnih bistvenih zdravstvenih in varnostnih zahtev, ter določi, ali take spremembe zahtevajo nadaljnje preiskave. V tem primeru priglašeni organ ustrezno obvesti proizvajalca.

Proizvajalec obvesti priglašeni organ, ki hrani tehnično dokumentacijo v zvezi s certifikatom o EU-pregledu tipa, o kakršnih koli spremembah odobrenega tipa in o kakršnih koli spremembah tehnične dokumentacije, ki bi lahko vplivale na skladnost osebne varovalne opreme z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami ali s pogoji veljavnosti certifikata. Take spremembe zahtevajo dodatno odobritev v obliki dodatka k izvirnemu certifikatu o EU-pregledu tipa.

Proizvajalec zagotovi, da OVO še naprej izpolnjuje veljavne bistvene zdravstvene in varnostne zahteve glede na najnovejše stanje na področju tehnološkega razvoja.

Proizvajalec priglašeni organ zaprosi za pregled certifikata o EU-pregledu tipa v enem od naslednjih primerov:
- v primeru spremembe odobrenega tipa iz točke 7.2, Priloge V, Uredbe 2016/425,
- v primeru spremembe stanja na področju tehnološkega razvoja iz točke 7.3 Priloge V, Uredbe 2016/425,
- najpozneje pred datumom izteka veljavnosti certifikata.

Da bi lahko priglašeni organ izpolnil svoje naloge, proizvajalec predloži vlogo nič prej kot dvanajst mesecev in nič pozneje kot šest mesecev pred datumom izteka veljavnosti certifikata o EU-pregledu tipa.

Revision of the current certificate of EU type-examination

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type- examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.

The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.

The manufacturer shall ask the notified body to review the EU type-examination certificate either:
- *in the case of a modification to the approved type referred to in point 7.2, Annex V, Regulation (EU) 2016/425,*
- *in the case of a change in the state of the art referred to in point 7.3, Annex V, Regulation (EU) 2016/425,*
- *at the latest, before the date of expiry of the certificate.*

In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.

Podaljšanje obstoječega certifikata o EU-pregleda tipa

Novo izdani certifikat in, kjer je to ustrezno, podaljšani certifikat veljata največ pet let.

Renewal of the current EU-type examination certificate

The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.

4. OPIS PROCESA / *PROCESS DESCRIPTION*

EU-pregled tipa ***EU type-examination***	**Opombe** ***Comments***
Seznanitev s postopkom *Process information*	
Vloga s strani proizvajalca *Application from the manufacturer*	Z zahtevano dokumentacijo *With the required documentation*
Sprejem in pregled vloge *Acceptance and review of the application*	Pregled pristojnosti organa in pregled popolnosti vloge *Verifying the competences of the body and checking the completeness of the application*
Določitev certifikacijskega strokovnjaka *Designation of the Certification expert*	Strokovnjak, ki vodi postopek *Procedure leading expert*
Pregled spremne dokumentacije *Review of the supporting documentation*	Poziv za dopolnitev vloge *Call for completion of the application*
Potrditev vloge in začetek postopka *Confirmation of the application and beginning of the process*	Potrditev s strani priglašenega organa *Confirmation from the Notified body*
Plan postopka *Process plan*	Potrditev s strani proizvajalca *Confirmation from the manufacturer*
Izvedba postopka (vrednotenje) *Performance of the process (evaluation)*	Priglašeni organ *Notified body*
Izvedba postopka (preskušanje) *Performance of the process (testing)*	Akreditiran preskusni laboratorij *Accredited testing laboratory*
Poročilo certifikacijskega strokovnjaka *Report of the Certification expert*	O izpolnjevanju bistvenih zahtev *On fulfilling essential requirements*
Pregled poročila s strani vodje priglašenega organa *Review by the Notified body head*	Priprava certifikata *Preparation of the certificate*
Podpis certifikata *Signature of the certificate*	Odgovorna oseba priglašenega organa *Responsible person of the notified body*
Izdaja certifikata o EU-pregledu tipa *Certificate issue of EU type-examination*	Uvrstitev v register certifikatov *Inclusion in the Register of Certificates*
Veljavnost certifikata 5 let od izdaje *Validity 5 years from the date of issue*	
Revizija certifikata *Revision of the certificate*	Proizvajalec poda novo vlogo *Manufacturer submits a new application*
Podaljšanje veljavnosti certifikata *Extension of validity of the certificate*	Proizvajalec poda novo vlogo *Manufacturer submits a new application*

V kateremkoli koraku se lahko izda odločba o zavrnitvi, če proizvajalec ne izpolnjuje zahtev oziroma ne izpolnjuje predpisanih rokov za odpravo neskladnosti. O tem priglašen organ obvesti regulatorja.
A rejection decision may be issued at any step if the manufacturer does not meet the requirements or does not meet the prescribed deadlines for the elimination of non-compliance. The notified body shall inform the regulator thereof.