CERTIFIKACIJSKA SHEMA: pregled tipa
CERTIFICATION SCHEME: type-examination

1. ZAHTEVE IN VODILA / *CRITERIA AND GUIDELINES*

1.1. Zahteve za certificiranje / *Certification criteria*

Direktiva (ES) 2001/95 evropskega parlamenta in sveta **o splošni varnosti proizvodov** (*v nadaljnjem* Direktiva (ES) 2001/95)
*Directive (EU) 2001/95 of the European parliament and of the council **on general product safety** (hereinafter referred to as Directive (EU) 2001/95)*

ali Nacionalni zakon / *or national Legislation*

Zakon o splošni varnosti izdelkov (Ur. l. RS, št. 101/03) v Sloveniji
Act on General Product Safety (Official Gazette of the RS, No 101/03) in Slovenia

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

Poglavje II (Direktiva (ES) 2001/95)
Chapter II (Directive (ES) 2001/95)

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

Poglavje II: Splošna varnostna zahteva, merila za ugotavljanje skladnosti in evropski standardi
Chapter II: General safety requirement, conformity assessment criteria and European standards

1.4. Standard za sistem vodenja kakovosti
Standard for quality management system

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

1.5. Evropski standardi oziroma normativni dokumenti za izdelek
European standards and normative documents for product

EN 14059:2002, Dekorativne oljne svetilke – Varnostne zahteve in preskusne metode
EN 14059:2002, Decorative oil lamps – Safety requirements and test methods

2. NALOGE PROIZVAJALCA IN CERTIFIKACIJSKEGA ORGANA
THE MANUFACTURER AND CERTIFICATION BODY SHALL

2.1. Naloge proizvajalca / *The manufacturer shall*

- Proizvajalec vloži zahtevek za pregled tipa pri enem certifikacijskem organu, ki ga izbere sam.
- Proizvajalec obvesti certifikacijski organ, ki hrani tehnično dokumentacijo v zvezi s certifikatom o pregledu tipa, o kakršnih koli spremembah tipa in o kakršnih koli spremembah tehnične dokumentacije, ki bi lahko vplivale na skladnost proizvoda z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami ali s pogoji veljavnosti certifikata. Take spremembe zahtevajo dodatno odobritev v obliki dodatka k izvirnemu certifikatu o pregledu tipa.
- Proizvajalec zagotovi, da proizvod še naprej izpolnjuje veljavne bistvene zdravstvene in varnostne zahteve glede na najnovejše stanje na področju tehnološkega razvoja.
- Proizvajalec certifikacijski organ zaprosi za pregled certifikata o pregledu tipa v enem od naslednjih primerov:
    - v primeru spremembe odobrenega tipa ali spremembe na področju tehnološkega razvoja, ki bistveno vpliva na ugotovljeno skladnost,
    - najpozneje pred datumom izteka veljavnosti certifikata. Da bi lahko certifikacijski organ izpolnil svoje naloge, proizvajalec predloži vlogo nič prej kot dvanajst mesecev in nič pozneje kot šest mesecev pred datumom izteka veljavnosti certifikata o pregledu tipa.
- Kadar gre za manjše spremembe proizvoda in ni izpolnjen pogoj iz predhodne alineje, se lahko uporabi poenostavljeni postopek pregleda. Proizvajalec certifikacijskemu organu predloži naslednje:
    - svoje ime in naslov ter podatke za identifikacijo zadevnega certifikata o pregledu tipa,
    - izjavo, da odobreni tip, vključno z materiali, pod-komponentami ali podsestavi, pa tudi uporabljeni ustrezni standardi ali tehnične specifikacije niso bili spremenjeni,
    - izjavo, da ni bilo spremembe stanja na področju tehnološkega razvoja,
    - izvode skic in fotografij sedanjih proizvodov, oznake proizvodov in informacije, ki jih zagotovi proizvajalec, kadar vse to certifikacijskemu organu še ni bilo predloženo,
- Proizvajalec še deset let po tem, ko je bil proizvod dan na trg, omogoča nacionalnim organom dostop do izvoda certifikata o 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 type-examination with a single certification body of his choice.*
- *The manufacturer shall inform the certification body that holds the technical documentation relating to the 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 product 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 type-examination certificate.*

- *The manufacturer shall ensure that the product continues to fulfil the applicable essential health and safety requirements in the light of the state of the art.*
- *The manufacturer shall ask the certification body to review the type-examination certificate either:*
  - *in the case of a modification to the approved type or a change in the state of the art which significantly affects the conformity established,*
  - *at the latest, before the date of expiry of the certificate. In order to allow the certification 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 type-examination certificate.*
- *In the case of minor changes to the products and where the condition set out in the preceding indent are not meet, a simplified examination procedure may be applied. The manufacturer shall supply the certification body with the following:*
  - *his name and address and data identifying the type-examination certificate concerned,*
  - *confirmation that there has been no modification to the approved type, including materials, sub-components or sub-assemblies, nor to the relevant standards or other technical specifications applied,*
  - *confirmation that there has been no change in the state of the art,*
  - *where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer,*
- *The manufacturer shall keep a copy of the type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the product 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.*

2.1.1. Tehnična dokumentacija proizvoda

Technical documentation of the product

Tehnična dokumentacija mora vsebovati vsaj:
- splošen opis proizvoda z bistvenimi sestavnimi deli in tehničnimi podatki,
- opis zasnove konstrukcije proizvoda,
- tehnične risbe, načrt sestavnih delov, podsestavov in način sestave,
- opis proizvodnih postopkov, ki zagotavljajo skladnost proizvodnje (če so potrebni),
- rezultate morebitnih projektnih izračunov, pregledov … (če obstajajo),
- seznam in dokaze o izpolnjevanju vseh bistvenih zahtev za proizvod,
- oceno tveganja pri primerni uporabi in morebitne omejitve, ki jih poda proizvajalec,
- poročilo(a) (certifikat) o preskusih, ki dokazujejo skladnost z naznačenimi pogoji delovanja (uporabe) in standardi (če že obstajajo),
- fotografijo proizvoda, embalaže in etikete na proizvodu ali embalaži (kar obstaja),
- navodila za uporabo,
- izjavo o skladnosti proizvoda,
- druga dokazila, ki lahko služijo pri ugotavljanju skladnosti proizvoda.

Technical documentation includes at least:
- *a general description of the product with essential components and technical data,*
- *a description of the design of the construction of the product,*
- *technical drawings, a components plan, sub-assemblies and method of assembly,*

- *a description of the manufacturing processes to ensure conformity (if any),*
- *the results of any design calculations, examinations, etc (if any),*
- *a list and evidence of compliance with all the essential requirements,*
- *the risk assessment for appropriate use and restrictions given by the manufacturer,*
- *a test report(s) (certificate) demonstrating compliance with the specified operating conditions (usage) and standards (if any already exists),*
- *a photograph of the product, the packaging and the label on the product or packaging (whichever exists),*
- *instructions for use,*
- *a declaration of conformity of the product,*
- *other evidence which may serve to establish the conformity of the product.*

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 ali posredovati dokazila o izpolnjevanju obveznosti proizvajalca.

- *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 or provide evidence of the fulfilment of the manufacturer's obligations.*

2.3. Naloge certifikacijskega organa / *Certification body shall*

- Pregleda tehnično dokumentacijo, da oceni ustreznost namene proizvoda.
- Preveri, ali je bil vzorec izdelan v skladu s tehnično dokumentacijo ali 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 standardov, te pravilno upošteval.
- Izvede ali naroči ustrezne preglede in preskuse, da bi, če rešitve iz ustreznih standardov niso bile uporabljene, preveril, ali rešitve, ki jih je sprejel proizvajalec, vključno s tistimi iz drugih uporabljenih tehničnih specifikacij, izpolnjujejo ustrezne bistvene zahteve in ali so bile uporabljene pravilno.
- Certifikacijski organ pripravi poročilo o vrednotenju, ki navaja ugotovitve in morebitne ukrepe.
- Kadar tip izpolnjuje veljavne bistvene zahteve, certifikacijski organ proizvajalcu izda certifikat o pregledu tipa. Novo izdani certifikat in, kjer je to ustrezno, podaljšani certifikat veljata največ pet let.
- Če tip ne izpolnjuje veljavnih bistvenih zahtev, certifikacijski organ zavrne izdajo certifikata o pregledu tipa in ustrezno obvesti vložnika s podrobno utemeljitvijo zavrnitve.
- Certifikacijski organ spremlja kakršne koli spremembe splošno sprejetih najnovejših tehničnih dosežkov, ki kažejo, da odobreni tip ne izpolnjuje več veljavnih bistvenih zahtev, ter določi, ali take spremembe zahtevajo nadaljnje preiskave. V tem primeru certifikacijski organ ustrezno obvesti proizvajalca.

- Certifikacijski organ pregleda tip proizvoda in, kadar je potrebno glede na opravljene spremembe, izvede ustrezne preskuse za zagotovitev, da odobreni tip še naprej izpolnjuje veljavne bistvene zahteve. Če certifikacijski organ ugotovi, da odobreni tip še naprej izpolnjuje veljavne zahteve, certifikat o pregledu tipa podaljša. Certifikacijski organ zagotovi, da je postopek pregleda opravljen pred datumom izteka veljavnosti certifikata o pregledu tipa.
- Če po pregledu certifikacijski organ ugotovi, da certifikat o pregledu tipa ni več veljaven, ta organ certifikat umakne, proizvajalec pa preneha dajati na trg zadevne proizvode.
- Komisija ali države članice lahko na zahtevo dobijo izvod certifikatov o 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 certifikacijski organ.
- Certifikacijski organ hrani izvod certifikata o 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 product for its intended purpose.*
- *Verify that the specimen(s) have been manufactured in conformity with the technical documentation or 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 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 standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential requirements and have been applied correctly.*
- *The certification body shall prepare the evaluation report setting out findings and any actions to be taken.*
- *Where the type meets the applicable essential requirements, the certification body shall issue an 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 requirements, the certification body shall refuse to issue an type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.*
- *The certification 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 requirements and shall determine whether such changes require further investigation. If so, the certification body shall inform the manufacturer accordingly.*
- *The certification body shall examine the product 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 requirements. If the certification body is satisfied that the approved type continues to fulfil the applicable requirements, it shall renew the type-examination certificate. The certification body shall ensure that the review procedure is finalised before the expiry date of the type-examination certificate.*

- *If, following the review, the certification body concludes that the type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the product concerned.*
- *The Commission and the Member States may, on request, obtain a copy of the 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 certification body.*
- *The certification body shall keep a copy of the 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*

Pregled tipa

Pregled tipa je tisti del postopka ugotavljanja skladnosti, pri katerem certifikacijski organ pregleda tehnično načrtovanje proizvoda ter preveri in potrdi, da tehnično načrtovanje proizvoda izpolnjuje bistvene zahteve, ki veljajo zanj.

Pregled tipa se izvaja z oceno ustreznosti tehničnega načrtovanja proizvoda s pregledom tehnične dokumentacije in s pregledom vzorca, reprezentativnega za predvideno proizvodnjo celotnega proizvoda (tip proizvodnje).

Kadar tip izpolnjuje veljavne bistvene zahteve, certifikacijski organ proizvajalcu izda certifikat o pregledu tipa.

Type-examination

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

Where the type meets the applicable essential requirements, the certification body shall issue an type-examination certificate to the manufacturer.

Revizija obstoječega certifikata o pregleda tipa

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

Proizvajalec obvesti certifikacijski organ, ki hrani tehnično dokumentacijo v zvezi s certifikatom o pregledu tipa, o kakršnih koli spremembah odobrenega tipa in o kakršnih koli spremembah tehnične dokumentacije, ki bi lahko vplivale na skladnost proizvoda z veljavnimi bistvenimi zahtevami ali s pogoji veljavnosti certifikata. Take

spremembe zahtevajo dodatno odobritev v obliki dodatka k izvirnemu certifikatu o pregledu tipa.

Proizvajalec zagotovi, da proizvod še naprej izpolnjuje veljavne bistvene zahteve glede na najnovejše stanje na področju tehnološkega razvoja.

Proizvajalec certifikacijski organ zaprosi za pregled certifikata o pregledu tipa v enem od naslednjih primerov:
- v primeru spremembe odobrenega tipa ali stanja na področju tehnološkega razvoja,
- najpozneje pred datumom izteka veljavnosti certifikata.

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

Revision of the current certificate of type-examination

The certification 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 requirements, and shall determine whether such changes require further investigation. If so, the certification body shall inform the manufacturer accordingly.

The manufacturer shall inform the certification body that holds the technical documentation relating to the 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 product with the applicable essential requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original type-examination certificate.

The manufacturer shall ensure that the product continues to fulfil the applicable essential requirements in light of the state of the art.

The manufacturer shall ask the certification body to review the type-examination certificate either:
- *in the case of a modification to the approved type or a change in the state of the art,*
- *at the latest, before the date of expiry of the certificate.*

In order to allow the certification 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 type-examination certificate.

Podaljšanje obstoječega certifikata o pregleda tipa

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

Renewal of the current 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*

Pregled tipa ***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 in popolnosti vloge *Verifying the competences and 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 certifikacijskega organa *Confirmation from the Certification body*
Plan postopka *Process plan*	Potrditev s strani proizvajalca *Confirmation from the manufacturer*
Izvedba postopka (vrednotenje) *Performance of the process (evaluation)*	Certifikacijski organ *Certification body*
Izvedba postopka (preskušanje) *Performance of the process (testing)*	Preskusni laboratorij *Testing laboratory*
Poročilo certifikacijskega strokovnjaka *Report of the Certification expert*	O izpolnjevanju bistvenih zahtev *On fulfilling essential requirements*
Pregled poročila s strani vodje certifikacijskega organa *Review of the report by the certification body head*	Priprava certifikata *Preparation of the certificate*
Podpis certifikata *Signature of the certificate*	Odgovorna oseba certifikacijskega organa *Responsible person of the certification body*
Izdaja certifikata o pregledu tipa *Certificate issue of 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.
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.