CERTIFIKACIJSKA SHEMA – Modul D: Skladnost s tipom na podlagi zagotavljanja kakovosti proizvodne
CERTIFICATION SCHEME – Module D: Declaration of conformity to type based on quality assurance of the production process

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 (ES) 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 VIII, Modul D, Skladnost s tipom na podlagi zagotavljanja kakovosti proizvodnje
Annex VIII, Module D, Conformity to type based on quality assurance of the production process

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 upravlja odobren sistem kakovosti za proizvodnjo, pregled končnega proizvoda in preskušanje zadevne OVO iz točke 3, Priloge VIII, Uredbe (ES) 2016/425 ter je nadzorovan v skladu s točko 4, Priloge VIII, Uredbe (ES) 2016/425.
- Proizvajalec predloži zahtevek za oceno sistema kakovosti pri enem samem priglašenem organu, ki ga sam izbere.
- Proizvajalec je obveščen o rezultatih ocene. Obvestilo vsebuje ugotovitve presoje in utemeljeno odločitev o oceni. Proizvajalec ukrepa tako, da izpolni obveznosti, ki izhajajo iz odobrenega sistema kakovosti, in ohrani njegovo primernost in učinkovitost.
- Proizvajalec priglašeni organ, ki je odobril sistem kakovosti, obvešča o vseh načrtovanih spremembah sistema kakovosti.
- Proizvajalec priglašenemu organu za namene ocene omogoči dostop do krajev proizvodnje, pregledovanja, preskušanja in skladiščenja ter mu zagotovi vse potrebne informacije, zlasti:
    - dokumentacijo o sistemu kakovosti;
    - zapise kakovosti, kot so poročila o pregledih in podatki o preskusih, podatki o umerjanju opreme in poročila o strokovni usposobljenosti osebja.
- Proizvajalec namesti oznako CE in na odgovornost priglašenega organa (iz točke 3.1 Uredbe (ES) 2016/425) identifikacijsko številko tega organa na vsak posamezni kos OVO, ki je v skladu s tipom, opisanim v certifikatu o EU-pregledu tipa, in izpolnjuje veljavne zahteve iz te uredbe.
- Proizvajalec za vsak model OVO sestavi pisno izjavo EU o skladnosti in še deset let po tem, ko je bila OVO dana na trg, nacionalnim organom omogoča dostop do nje. Izjava EU o skladnosti opredeljuje model OVO, za katerega je bila sestavljena. Na zahtevo se pristojnim organom predloži izvod izjave EU o skladnosti.
- Proizvajalec še deset let po tem, ko je bila OVO dana na trg, omogoča državnim organom dostop do:
    - dokumentacije (iz točke 3.1 Uredbe (ES) 2016/425),
    - informacij v zvezi s spremembami (iz točke 3.5 Uredbe (ES) 2016/425, kakor je bila odobrena,
    - odločitev in poročil priglašenega organa (iz točk 3.5, 4.3 in 4.4. Uredbe (ES) 2016/425).

- Proizvajalec izpolnjuje splošne zahteve certifikacijskega organa, objavljene na spletni strani certifikacijskega organa.

- *The manufacturer shall operate an approved quality system for production, final product inspection and testing of the PPE concerned as specified in point 3 of the Regulation (EU) 2016/425, and shall be subject to surveillance as specified in point 4 of the Regulation (EU) 2016/425.*
- *The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.*
- *The result of that assessment shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.*
- *The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.*
- *The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:*
    - *the quality system documentation,*
    - *the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.*
- *The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1 of the Regulation (EU) 2016/425, the latter's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.*
- *The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.*
- *The manufacturer shall, for 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:*
    - *the documentation referred to in point 3.1 (Regulation (EU) 2016/425),*
    - *the information related to the change referred to in point 3.5 (Regulation (EU) 2016/425), as approved,*
    - *the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4 (Regulation (EU) 2016/425).*
- *The manufacturer complies with the general requirements of the certification body, as published on the certification body's website.*

2.2. Naloge proizvajalca

The manufacturer shall

- Proizvajalec namesti oznako CE in na odgovornost priglašenega organa (iz točke 3.1 Uredbe (ES) 2016/425) identifikacijsko številko tega organa na vsak posamezni kos OVO, ki je v skladu s tipom, opisanim v certifikatu o EU-pregledu tipa, in izpolnjuje veljavne zahteve iz te uredbe.

- Proizvajalec za vsak model OVO sestavi pisno izjavo EU o skladnosti in še deset let po tem, ko je bila OVO dana na trg, nacionalnim organom omogoča dostop do nje. Izjava EU o skladnosti opredeljuje model OVO, za katerega je bila sestavljena. Na zahtevo se pristojnim organom predloži izvod izjave EU o skladnosti.
- Proizvajalec še deset let po tem, ko je bila OVO dana na trg, omogoča državnim organom dostop do:
  - dokumentacije (iz točke 3.1 Uredbe (ES) 2016/425),
  - informacij v zvezi s spremembami (iz točke 3.5 Uredbe (ES) 2016/425, kakor je bila odobrena,
  - odločitev in poročil priglašenega organa (iz točk 3.5, 4.3 in 4.4. Uredbe (ES) 2016/425).
- Zahtevek za oceno sistema kakovosti proizvajalec predloži pri enem samem priglašenem organu, ki ga sam izbere.
- Proizvajalec priglašeni organ, ki je odobril sistem kakovosti, obvešča o vseh načrtovanih spremembah sistema kakovosti.

- *The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.*
- *The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.*
- *The manufacturer shall, for 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:*
  - *the documentation referred to in point 3.1 (Regulation (EU) 2016/425),*
  - *the information related to the change referred to in point 3.5 (Regulation (EU) 2016/425), as approved,*
  - *the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4. (Regulation (EU) 2016/425).*
- *The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.*
- *The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.*

2.3. Naloge priglašenega organa / *Notified body shall*

- Priglašeni organ oceni sistem kakovosti, da ugotovi, ali sistem izpolnjuje zahteve, navedene v točki 3.2 Priloge VIII Uredbe (ES) 2016/425.
- Priglašeni organ domneva skladnost s tistimi zahtevami glede elementov sistema kakovosti, ki so skladni z ustreznimi specifikacijami ustreznega harmoniziranega standarda.
- Priglašeni organ oceni kakršno koli predlagano spremembo in odloči, ali bo spremenjeni sistem kakovosti še vedno izpolnjeval zahteve iz točke 3.2 Uredbe (ES) 2016/425 ali pa je potrebna ponovna ocena.

- Priglašeni organ proizvajalca pooblasti, da namesti njegovo identifikacijsko številko na vsak posamezni kos OVO, ki je v skladu s tipom, opisanim v certifikatu o EU-pregledu tipa, in izpolnjuje veljavne zahteve iz te uredbe.
- Priglašeni organ opravlja redne preglede vsaj enkrat letno, s čimer zagotovi, da proizvajalec vzdržuje in izvaja sistem kakovosti, poročila o teh pregledih pa pošilja proizvajalcu.
- Poleg tega lahko priglašeni organ nenapovedano obišče proizvajalca. Med takšnimi obiski sme priglašeni organ, če je potrebno, opraviti ali naročiti preskuse OVO, da preveri pravilno delovanje sistema kakovosti. Priglašeni organ proizvajalcu pošlje poročilo o obisku; če so bili izvedeni preskusi, pošlje tudi poročilo o njih.
- Vsak priglašeni organ svoje priglasitvene organe obvesti o izdanih ali umaknjenih odobritvah sistema kakovosti in redno ali na zahtevo svojemu priglasitvenemu organu omogoča dostop do seznama zavrnjenih, začasno preklicanih ali drugače omejenih odobritev sistema kakovosti. Priglašeni organ druge priglašene organe obvesti o odobritvah sistema kakovosti, ki jih je zavrnil, začasno preklical, umaknil ali drugače omejil, ter jih na zahtevo obvesti o odobritvah sistema kakovosti, ki jih je izdal.

- *The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 (Regulation (EU) 2016/425).*
- *It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.*
- *The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 (Regulation (EU) 2016/425) or whether a reassessment is necessary.*
- *The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.*
- *The notified body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.*
- *In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.*
- *he notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such quality system approvals refused, suspended or otherwise restricted. The notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.*

3. VRSTE POSTOPKOV / *TYPES OF PROCEDURES*

Začetna presoja

Skladnost s tipom na podlagi zagotavljanja kakovosti proizvodnega procesa, se izvede na zahtevo proizvajalca, in je del postopka ugotavljanja skladnosti, v okviru katerega proizvajalec izpolni točke 2., 5. ter 6. Priloge VIII, Uredbe (ES) 2016/425 in izjavi, da je zadevna OVO v skladu s tipom, opisanim v certifikatu o EU-pregledu tipa in izpolnjuje veljavne zahteve Uredbe (EU) 2016/425. Ob pogoju uspešno zaključenega postopka začetne presoje se izda certifikat o odobritvi sistema kakovosti, ki je veljaven tri leta od začetne presoje pod pogojem, da so izpolnjene vse relevantne zahteve Uredbe (ES) 2016/425.

Vsi elementi, zahteve in določbe, ki jih je sprejel proizvajalec, so sistematično in urejeno dokumentirani kot pisno dokumentirane politike, postopki in navodila. Dokumentacija sistema kakovosti omogoča dosledno razlago programov kakovosti, načrtov, priročnikov in zapisov.

The initial assessment

Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5 and 6, Annex VIII, Regulation (EU) 2016/425, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the EU type- examination certificate and satisfies the applicable requirements of this Regulation. If the initial assessment is successfully completed, the certificate of quality system approval is issued. It is valid three years from the beginning of the assessment process, if all the conditions satisfy the requirements of the Regulation (EU) 2016/425.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

Redne nadzorne presoje

Priglašeni organ opravlja redne preglede vsaj enkrat letno, s čimer zagotovi, da proizvajalec vzdržuje in izvaja sistem kakovosti, poročila o teh pregledih pa pošilja proizvajalcu.

Namen nadzora je zagotoviti, da proizvajalec ustrezno izpolnjuje obveznosti, ki izhajajo iz odobrenega sistema kakovosti.

Regular surveillance assessment

The notified body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

Širitev/sprememba obsega
Proizvajalec priglašeni organ, ki je odobril sistem kakovosti, obvešča o vseh načrtovanih spremembah sistema kakovosti. Priglašeni organ, na zahtevo proizvajalca, oceni kakršno koli predlagano spremembo in odloči, ali bo spremenjeni sistem kakovosti še vedno izpolnjeval zahteve iz točke 3.2, Priloge VIII, Uredbe (ES) 2016/425 ali pa je potrebna ponovna ocena.

O svoji odločitvi obvesti proizvajalca. Obvestilo vsebuje rezultate pregleda in obrazložitev odločitve.

Expanding/change of the production
The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2, Annex VIII, Regulation (EU) 2016/425, or whether a reassessment is necessary. It shall notify the manufacturer of its decision.

The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Izredna nadzorna presoja
Priglašeni organ lahko nenapovedano obišče proizvajalca. Med takšnimi obiski sme priglašeni organ, če je potrebno, opraviti ali naročiti preskuse OVO, da preveri pravilno delovanje sistema kakovosti. Priglašeni organ proizvajalcu pošlje poročilo o obisku; če so bili izvedeni preskusi, pošlje tudi poročilo o njih. Presoja vključuje ocenjevalni obisk v obratih proizvajalca.

Irregular surveillant assessment
The notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report. The audit shall include an assessment visit to the manufacturer's premises.

4. OPIS PROCESA / *PROCESS DESCRIPTION*

Začetna presoja, širitev / sprememba obsega ***The initial assessment, expanding/change of the scope***	**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 ocenjevalca *Designation of the Assessor*	Ocenjevalec, ki vodi postopek *Procedure leading assessor*
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 (ocenjevanje) *Performance of the process (assessment)*	Morebitni korektivni ukrepi *Possible corrective actions*
Zapis in odprava neskladnosti *Reporting and elimination of disconformities*	Proizvajalec poroča v roku *Manufacturer shall report within deadline*
Pregled poročila proizvajalca *Review of manufacturer's report*	Morebiten poziv za dodatna pojasnila *A possible call for further clarification*
Poročilo ocenjevalca *Report of the Assessor*	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 odobritvi sistema kakovosti *Certificate issue of quality system approval*	Uvrstitev v register certifikatov *Inclusion in the Register of Certificates*
Veljavnost certifikata 3 let od izdaje *Validity 3 years from the date of issue*	Z rednimi letnimi ocenjevanji *With annual assessments*
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.