CERTIFIKACIJSKA SHEMA – Modul C2: Skladnost s tipom na podlagi notranjega nadzora proizvodnje in nadzorovanih preskusov proizvodov v naključno izbranih časovnih presledkih
CERTIFICATION SCHEME – Module C2: Conformity to type based on internal production control plus supervised product checks at random intervals

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 VII, Modul C2, Skladnost s tipom na podlagi notranjega nadzora proizvodnje in nadzorovanih preskusov proizvodov v naključno izbranih časovnih presledkih
Annex VII, Module C2, Conformity to type based on internal production control plus supervised product checks at random intervals

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 sprejme vse potrebne ukrepe, da se s proizvodnim procesom in njegovim spremljanjem zagotovi homogenost proizvodnje in skladnost proizvedene OVO s tipom, opisanim v certifikatu o EU-pregledu tipa, in veljavnimi zahtevami iz Uredbe (ES) 2016/425.
- Preden proizvajalec da OVO na trg, vloži zahtevek za nadzorovane preskuse proizvodov v naključno izbranih časovnih presledkih pri enem samem priglašenem organu, ki ga izbere sam.
- Proizvajalec nacionalnim organom omogoča dostop do poročila o preskusu deset let po tem, ko je bila OVO dana na trg.
- Proizvajalec namesti oznako CE in na odgovornost priglašenega organa iz točke 3, Priloge VII, 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 deset let po tem, ko je bila oprema dana na trg, nacionalnim organom omogoča dostop do nje. Izjava EU o skladnosti opredeljuje model osebne varovalne opreme, za katerega je bila sestavljena. Na zahtevo se pristojnim organom predloži izvod izjave EU o skladnosti.
- Proizvajalec omogoči certifikacijskemu organu izvedbo vzorčenja in preskušanja skladno s certifikacijskim postopkom.
- Proizvajalec izpolnjuje splošne zahteve certifikacijskega organa, objavljene na spletni strani certifikacijskega organa.

- *The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type- examination certificate and with the applicable requirements of this Regulation.*
- *Before placing PPE on the market, the manufacturer shall lodge an application for supervised product checks at random intervals with a single notified body of his choice.*
- *The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.*

- *The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, Annex VII, 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.*
- *The manufacturer shall allow the certification body to carry out sampling and testing in accordance with the certification procedure.*
- *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*

- Priglašeni organ izvede preskuse proizvodov, da preveri homogenost proizvodnje in skladnost OVO s tipom, ki je opisan v certifikatu o EU-pregledu tipa, ter z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami.
- Preskusi proizvodov se izvedejo najmanj enkrat na leto v naključno izbranih časovnih presledkih, ki jih določi priglašeni organ. Prvi preskusi proizvodov se opravijo največ eno leto po datumu izdaje certifikata o EU-pregledu tipa.
- Priglašeni organ na mestu, dogovorjenem med njim in proizvajalcem, izbere ustrezen statistični vzorec proizvedene OVO. Pregledajo se vsi kosi vzorčne OVO in opravijo se primerni preskusi, ki so določeni v ustreznih harmoniziranih standardih, in/ali enakovredni preskusi iz drugih ustreznih tehničnih specifikacij, da se preveri skladnost OVO s tipom, opisanim v certifikatu o EU-pregledu tipa, ter z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami.
- Kadar priglašeni organ iz točke 3, Priloge VII, Uredbe (ES) 2016/425 ni organ, ki je izdal certifikat o EU-pregledu tipa, v primeru težav v zvezi z ugotavljanjem skladnosti vzorca stopi v stik s tem organom.
- Če pregled in preskušanje pokažeta, da proizvodnja ni homogena ali da osebna varovalna oprema ni v skladu s tipom, opisanim v certifikatu o EU-pregledu tipa, ali z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami, priglašeni organ

sprejme ukrepe, primerne za ugotovljene napake, in o tem obvesti priglasitveni organ.
- Priglašeni organ proizvajalcu pošlje poročilo o preskusu.

- *The notified body shall carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.*
- *The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no more than one year after the date of issue of the EU type- examination certificate.*
- *An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.*
- *Where the notified body referred to in point 3, Annex VII, Regulation (EU) 2016/425, is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.*
- *If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.*
- *The notified body shall provide the manufacturer with a test report.*

3. VRSTE POSTOPKOV / *TYPES OF PROCEDURES*

Vzorčenja in preskušanja

Preden proizvajalec da osebno varovalno opremo na trg, vloži zahtevek za nadzorovane preskuse proizvodov v naključno izbranih časovnih presledkih pri enem samem priglašenem organu, ki ga izbere sam.

Priglašeni organ izvede preskuse proizvodov, da preveri homogenost proizvodnje in skladnost OVO s tipom, ki je opisan v certifikatu o EU-pregledu tipa, ter z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami.

Preskusi proizvodov se izvedejo najmanj enkrat na leto v naključno izbranih časovnih presledkih, ki jih določi priglašeni organ. Prvi preskusi proizvodov se opravijo največ eno leto po datumu izdaje certifikata o EU-pregledu tipa

Sampling and testing

Before placing PPE on the market, the manufacturer shall lodge an application for supervised product checks at random intervals with a single notified body of his choice.

The notified body shall carry out product checks to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.
The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no more than one year after the date of issue of the EU type-examination certificate.

Širitev/sprememba obsega
Če pregled in preskušanje pokažeta, da proizvodnja ni homogena ali da osebna varovalna oprema ni v skladu s tipom, opisanim v certifikatu o EU-pregledu tipa, ali z veljavnimi bistvenimi zdravstvenimi in varnostnimi zahtevami, priglašeni organ sprejme ukrepe, primerne za ugotovljene napake, in o tem obvesti regulatorja.

Expanding/change of the production
If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.

4. OPIS PROCESA / *PROCESS DESCRIPTION*

Vzorčenja in preskušanja ***Sampling and testing***	**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*	Proizvajalec obvešča o proizvodni *Production information by manufacturer*
Izvedba postopka (vzorčenje) *Performance of the process (sampling)*	Nenapovedano priglašeni organ *Unannounced 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 nadzoru *Certificate issue of control*	Uvrstitev v register certifikatov *Inclusion in the Register of Certificates*
Veljavnost certifikata 1 leto od izdaje *Validity 1 year 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.