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 (EU) 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 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 proizvod / *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

1.5.1. Industrijske zaščitne čelade (Opomba: Velja za proizvode, ki ustrezajo točkama zahtevam za kategorijo III)
Industrial safety helmets (Note: Applies to products complying with requirements for category III)

EN 397:2012+A1:2012, Industrijske zaščitne čelade
EN 397:2012+A1:2012, Industrial safety helmets

EN 960:2006, Modeli glav za preskušanje zaščitnih čelad
EN 960:2006, Headforms for use in the testing of protective helmets

EN ISO 472:2013, Polimerni materiali - Slovar
EN ISO 472:2013, Plastics — Vocabulary (ISO 472:1999)

EN ISO 9185:2007, Varovalna obleka – Ocenitev odpornosti materialov proti obrizgu staljene kovine
EN ISO 9185:2007, Protective clothing — Assessment of resistance of materials to molten metal splash

1.5.2. Elektroizolacijske čelade
Electrically insulating helmets

EN 50365:2023, Delo pod napetostjo - Elektroizolacijske čelade za delo na nizkonapetostnih inštalacijah
EN 50365:2024/AC:2024 Delo pod napetostjo - Elektroizolacijske čelade za delo na nizko- in srednjenapetostnih inštalacijah - Popravek AC
EN 50365:2023, Live Working - Electrically insulating helmets for use on low and medium voltage installations
EN 50365:2024/AC:2024 Live Working - Electrically insulating helmets for use on low and medium voltage installations

EN 397:2012+A1:2012, Industrijske zaščitne čelade
EN 397:2012+A1:2012, Industrial safety helmets

EN 443:2008, Gasilske čelade za gašenje v stavbah in drugih zgradbah
EN 443:2008, Helmets for fire fighting in buildings and other structures

EN 14052:2012+A1:2012, Industrijske čelade z visoko stopnjo zaščite
EN 14052:2012+A1:2012, High performance industrial helmets

EN 50110-1:2023, Obratovanje električnih postrojev - 1. del: Splošne zahteve
EN 50110-1:2023, Operation of electrical installations - Part 1: General requirements

EN 60060-1:2010, Visokonapetostne preskusne tehnike - 1. del: Splošne definicije in preskusne zahteve
EN 60060-1:2010, High-voltage test techniques - Part 1: General definitions and test requirements

EN IEC 61318:2021, Delo pod napetostjo - Metode za ocenjevanje okvar in preverjanje delovne sposobnosti orodja, naprav in opreme
EN IEC 61318:2021, Live working - Methods for assessment of defects and verification of performance applicable to tools, devices and equipment (EC 61318:2021)

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 (EU) 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 (EU) 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 (EU) 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 (EU) 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, odda vlogo 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 proizvodnje
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 nadzorovanih preskusih proizvodov v naključnih presledkih *Issuing the Certificate of supervised product checks at random intervals*	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.