



## Splošni pogoji za ugotavljanje skladnosti merilnih instrumentov

### *General Terms and Conditions of Conformity Assessment of Measuring Instruments*

Splošni pogoji za ugotavljanje skladnosti merilnih instrumentov se nanašajo na certificiranje meril ter certificiranje procesov (t.j. odobritev in nadzor zagotavljanja kakovosti s strani proizvajalcev meril) na podlagi certifikacijske sheme, ki jo izbere vložnik. Certifikacijske sheme temeljijo na modulih ugotavljanja skladnosti iz Pravilnika o merilnih instrumentih (Uradni list RS, št. 19/16), ki povzema Direktivo o merilnih instrumentih 2014/32/EU (MID), oziroma Pravilnika o meroslovnih zahtevah za neavtomatske tehtnice (Ur. list RS, št. 25/16), ki povzema Direktivo o neavtomatskih tehtnicah 2014/31/EU (NAWI), (v nadaljevanju: pravilnik), za katere Urad RS za meroslovje (v nadaljevanju: urad) izvaja postopke ugotavljanja skladnosti v sklopu svoje priglasitve (priglašeni organ 1376).

Urad vodi postopke ugotavljanja skladnosti ob smiselni uporabi določb Zakona o splošnem upravnem postopku.

Ugotavljanje skladnosti merilnih instrumentov urad izvaja na podlagi principa "domneve o skladnosti" iz pravilnika. Seznam harmoniziranih standardov in normativnih dokumentov je objavljen tudi na spletnih straneh urada.

Certifikacijsko razmerje med uradom in vložnikom je urejeno s temi splošnimi pogoji ter potrjeno zahtevo vložnika.

*These General Terms and Conditions of Conformity Assessment of Measuring Instruments apply to the certification of measuring instruments and certification of processes (i.e. approval and surveillance of the quality assurance of manufacturers of measuring instruments) on the basis of a certification scheme chosen by the applicant. The certification schemes are based on conformity assessment modules of Rules on measuring instruments (Official Gazette of the RS, No. 19/16), which implements Measuring Instruments Directive 2014/32/EU (MID), and Rules on metrological requirements for non-automatic weighing instruments (Off. Gazette of RS No. 25/16), which implements Non-automatic Weighing Instruments Directive 2014/31/EU (NAWI), (hereinafter called "the Rules"), and for which MIRS carries out a conformity assessment procedures as the within the scope of its notification (Notified Body 1376).*

*MIRS conducts conformity assessment procedures, applying mutatis mutandis the provisions of the General Administrative Procedure Act.*

*Conformity assessment of measuring instruments MIRS carries out on basis of "presumption of conformity" as defined in the Rules. The list of harmonised standards and normative documents is available also on MIRS website.*

*The certification relationship between MIRS and the applicant is governed by these General Terms and Conditions and the confirmed application.*

### **Informacije o postopkih / Information about procedures**

Postopki se izvajajo na podlagi certifikacijske sheme, ki jo izbere vložnik. Informacije o certifikacijskih shemah so objavljene na spletni strani urada.

Certifikacijsko razmerje med uradom in vložnikom nastane s potrditvijo vložnikove zahteve s strani urada in je veljavno do preteka veljavnosti z njim povezanega certifikata. Za obnovev veljavnosti certifikata mora vložnik pred iztekom njegove veljavnosti uradu predložiti novo zahtevo. Certifikacijsko razmerje se predčasno prekine, če urad prekliče certifikat ali če za prekinitvev zaprosi vložnik. Certifikacijsko razmerje se predčasno prekine tudi, če je bila podelitev certifikata zavržena.

Urad med veljavnostjo certifikacijskega razmerja izvede vrednotenje in certifikacijski postopek ter nadzorne dejavnosti, ki jih predvideva izbrana certifikacijska shema in modul ugotavljanja skladnosti iz pravilnika, z namenom preveriti izpolnjevanje zahtev za certifikacijo.

Pogoji in postopki za podelitev, vzdrževanje, spremembo ali omejitev obsega, preklic certifikata ali zavrnitev certifikacije so določeni v izbrani certifikacijski shemi, modulu ugotavljanja skladnosti iz pravilnika in v razdelku Dolžnosti vložnikov teh Splošnih pogojev.

*The procedures are carried out on the basis of the certification scheme chosen by the applicant. Information on certification schemes is available on MIRS website.*

*The certification relationship between MIRS and the applicant is created with a confirmation of the application by MIRS and is valid until the validity of the certificate expires. To renew the validity of certificate, a new application must be submitted to MIRS before the validity of the certificate expires. The certification relationship ends prematurely if MIRS withdraws the certificate or if the applicant applies for the termination of the certification. The certification relationship also ends prematurely if the granting of the certificate is refused.*

*During the duration of the certification relationship, MIRS carries out the evaluation and certification procedure and the surveillance measures stipulated by the chosen certification scheme and conformity assessment module of the Rules in order to determine whether the requirements for a certification are fulfilled.*

*Conditions and procedures for granting, maintaining, changing or restricting the scope, withdrawing of the certificate or refusing the certification are defined in the chosen certification scheme, conformity assessment module of the Rules and in the section Obligations of Customers of this General Terms and Conditions.*

## **Dolžnosti vložnikov / Obligations of Customers**

Vložnik, proizvajalec oziroma njegov pooblaščen zastopnik, se zaveže izpolnjevati zahteve pravilnika, navedene v členih "Obveznosti proizvajalcev", "Pooblaščen zastopniki" in "Pravila in pogoji za namestitev oznake CE, dodatne meroslovne oznake in drugih oznak" in izbrane certifikacijske sheme, kar še posebej pomeni:

- da vložnik vedno izpolnjuje zahteve za certifikacijo, vključno z uvajanjem ustreznih sprememb, če mu jih urad sporoči;
- da če se certifikacija nanaša na proizvodnjo v teku, certificirano merilo še naprej izpolnjuje ustrezne zahteve,
- da vložnik uredi vse potrebno za:
  - o izvedbo vrednotenja in nadzora (če je potreben), vključno z možnostjo pregleda dokumentacije in zapisov ter dostopom do ustrezne opreme, lokacij, in osebja proizvajalca,
  - o dokumentiranje in ukrepanje glede pritožb;
  - o udeležbo opazovalcev pri izvedbi postopka, če je primerno;
- da vložnik nemudoma obvesti urad o spremembah, ki bi lahko vplivale na njegovo sposobnost izpolnjevanja zahtev za certifikacijo.

Izdani certifikat se lahko uporabi samo v obsegu veljavnosti certifikacije in na način, ki ne bo škodoval ugledu urada oziroma ogrozil zaupanja javnosti.

Vložnik se zavezuje, da ne bo zlorabil izdanega certifikata oziroma odobrene uporabe oznake CE in dodatne meroslovne oznake in da bo preprečil podajanje zavajajočih ali napačnih informacij o certifikaciji.

Če vložnik posreduje drugim kopije certifikacijskih dokumentov, morajo biti ti dokumenti razmnoženi v celoti.

Vložnik po izteku veljavnosti certifikata ne sme več uporabljati certifikata oziroma oznake CE in dodatne meroslovne oznake.

*The applicant, the manufacturer or its authorised representative, undertakes to comply with the requirements of the Rules's paragraphs "Obligations of manufacturers", "Authorised representatives", and "Rules and conditions for affixing the CE marking and the supplementary metrology marking and chosen certification scheme", in particular, that:*

- *the applicant always fulfils the certification requirements, including implementing appropriate changes when they are communicated by MIRS,*
- *if the certification applies to ongoing production, the certified measuring instruments continues to fulfil the relevant requirements,*
- *the applicant makes all necessary arrangements for*
  - o *the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location and personnel of producer,*
  - o *documenting and actioning on complaints,*
  - o *the participation of observers at the certification procedure, if applicable*
- *the applicant informs MIRS, without delay, of changes that may affect its ability to conform with the certification requirements*

*The issued certificate can be used only in accordance with the scope of validity of the certification and not in a manner which would discredit MIRS and/or would led itself to compromising public confidence.*

*The applicant undertakes to not apply the issued certificate and/or the granted use of CE marking and of the supplementary metrology marking abusively and to prevent a delivery of misleading or faulty information on the certification.*

*After the validity of the certificate expires, the applicant may not use the certificate any longer and may no longer apply the CE marking and of the supplementary metrology marking.*

*If the applicant provides copies of the certification documents to others, these documents shall be reproduced in full.*

## **Pristojbine / Fees**

Urad RS za meroslovje je organ v sestavi Ministrstva za gospodarski razvoj in tehnologijo in je neposredni proračunski porabnik.

Takse za zahteve, pritožbe in negativne odločbe se vložnikom zaračunavajo v skladu z Zakonom o upravnih taksah. Stroški postopka in izdaje certifikatov se vložnikom zaračunavajo v skladu z Uredbo o višini stroškov na področju meroslovja.

*MIRS is a body within Ministry of Economic Development and Technology and a direct budget-spending centre.*

*Administrative fees for applications, appeals and negative decisions are charged to the applicant according to the Administrative Fees Act. Fees for procedure costs and certificates are charged to the applicant according the Decree on the amount of expenses in the field of metrology.*

## **Pritožbe in pripombe / Appeals and complaints**

Zoper odločitve urada v postopkih certificiranja je ob smiselni uporabi določb Zakona o splošnem upravnem postopku dovoljena pritožba na Ministrstvo za gospodarski razvoj in tehnologijo v roku 15 dni od vročitve odločitve. Pritožba se vloži pri uradu.

Pripombe strank se obravnavajo v skladu z navodilom DN-AKRED 4.8-01, ki je dostopno na spletni strani urada.

*Subject to a sound application of provisions of the General Administrative Procedure Act, the applicant is entitled to raise an appeal to Ministry of Economic Development and Technology to the decisions made by MIRS in connection with the certification. Such objection is to be addressed to MIRS in a written form within 15 days after notification of the decision.*

*Customer's complaints are treated according to the procedure DN-AKRED 4.8-01, which is available on the MIRS website.*

## **Objava certifikatov ter dostop do informacij javnega značaja / Publication of certificates and access to public information**

Certifikati s prilogami, izdani v postopkih ugotavljanja skladnosti po modulih B, D, D1, E1 in G, so javno dostopni na spletni strani [www.mirs-info.si](http://www.mirs-info.si).

Urad je kot državni organ podvržen spoštovanju določb Zakona o dostopu do informacij javnega značaja, kar pomeni, da so, razen izjem kot so npr. poslovne informacije, opredeljene v Zakonu o poslovni skrivnosti, vse informacije, ki nastanejo pri delu urada ali urad zaradi svojega dela pride v stik z njimi, javne.

*Certificates with annexes issued in conformity assessment procedures according to Modules B, D, D1, E1 and G, are publicly available on web page [www.mirs-info.si](http://www.mirs-info.si).*

*As a governmental body, MIRS is subject to comply with the provisions of the Access to Public Information Act, which means that, with the exception such as business information defined in the Business Secrecy Act, all information that arises in the course of the work of MIRS or MIRS comes into contact with it due to its work, is public.*