Newsletter on medical devices regulatory environment, Ukraine

November 2018

Dear colleagues,

We would like to inform you on the news and current issues concerning medical devices in Ukraine.

1. Loss of accreditation and assignment by several conformity assessment bodies (notified bodies).
In 2018 three conformity assessment bodies for medical devices have lost their accreditation and assignment. Therefore, a number of issues have arisen related to the validity of certificates, the products circulation, and the transfer procedure.

SE "SMCC" (SE "State Medical Center of Certification" of the MOH of Ukraine, UA.TR.067): on March 23, 2018, the accreditation of the conformity assessment body was canceled by the decision of the National Accreditation Agency of Ukraine (NAAU), and then on April 27, 2018, the assignment was abrogated by order No. 588 of the Ministry of Economic Development.

By order No. 1102 dated June 11, 2018, of the Ministry of Health of Ukraine, the SE "SMCC" was incorporated into the State Ukrainian Association "Politekhmed" which acted as the custodian of the documentation of SE "SMCC". The manufacturer or its Authorised Representative can choose the conformity assessment body to transfer its certificate of conformity.

On September 21, 2018, the NAAU canceled the accreditation of the SE "SMCC" for compliance with the State Standard of Ukraine (DSTU) EN ISO/IEC 17021-1: 2015 (certification of quality management systems). However, many certificates of conformity for products have been issued on the basis of certificates for the quality management system according to ISO 13485 and/or ISO 9001 standards.

According to the information received from some Authorised Representatives, in October, the National Police sent requests concerning the importation of medical devices upon the certificates issued by the SE "SMCC" with reference to the decisions of the SE "SMCC" on the suspension of certificates. However, no information on the decisions made by the SE "SMCC" on cancellation of certificates has been received by the Authorised Representatives.

The reason for deciding to cancel product certificate can be a violation of the requirements of the State Standard of Ukraine (DSTU) EN ISO/IEC 17021-1:2015, i.e., the need in surveillance audits every 12 months from the date of the certificate issuance.

"Politoks" LLC (UA.TR.114): accreditation according to the State Standard of Ukraine (DSTU) EN ISO/IEC 17065:2014 (products certification) was canceled by the NAAU decision on August 17, 2018, and accreditation according to the State Standard of Ukraine (DSTU) EN ISO/IEC 17021-1:2015 (system certification) was canceled on September 11, 2018. The assignment of the conformity assessmentbody was annulled by order No. 1192 of the Ministry of Economic Development dated August 27, 2018.

By the letter dated August 28, 2018, the Ministry of Economic Development obliged "Politoks" LLC to transfer information on the conformity assessment documentation to the Ministry of Health for further processing and storage. According to information received from the Association of Market Operators of Medical Devices, (www.amomd.com), as of the beginning of October, the information has still not been transferred.

According to our information, as of the end of October, there were no other events related to the cancellation of the certificates on the conformity assessment for "Politoks" LLC. Please pay attention to the requirements

of the State Standard of Ukraine (DSTU) EN ISO/IEC 17021-1:2015 for performing surveillance audits every 12 months, which is the organic reason for the certificate termination.

SE "Cherkasystandartmetrolohiya" (State Enterprise "Cherkasy Research and Production Center of Standardization, Metrology and Certification", UA.TR.003): the scope of accreditation of the conformity assessment body specified in the Appendix to the attestation dated May 31, 2018, does not include medical devices. However, the NAAU website does not contain any information concerning suspension or cancellation of accreditation, which means the voluntary exclusion of medical devices from the scope of accreditation.
By order No. 805 of the Ministry of Economic Development dated June 12, 2018, the scope of assignment of the SE "Cherkasystandartmetrolohiya" was limited in terms of performing the conformity assessment to the Technical Regulations on Medical Devices (Resolution No. 753 of the CMU).

Therefore, we assume that in the spring of 2018, the SE "Cherkasystandartmetrolohiya" made a voluntary decision to exclude medical devices from the scope of accreditation, and on June 12, the Ministry of Economic Development and Trade excluded medical devices from the scope of assignment.

The certificates issued by the SE "Cherkasystandartmetrolohiya" are still valid, however, the conformity assessment body cannot perform surveillance audits in accordance with the requirements of the State Standard of Ukraine (DSTU) ISO/IEC 17021-1:2015.

If a certificate of conformity assessment was issued by one of the three above-mentioned conformity assessment bodies (SE "SMCC", "Politoks" LLC, or SE "Cherkasystandartmetrolohiya"), we recommend you to do the following:

1. Check the status of the certificate in the conformity assessment body register;
2. Examine the relationship between the products certificate and the system certificate (if such was issued), the provisions of the Certification Agreement between the manufacturer and the conformity assessment body, and the date of the next surveillance audit;
3. If for any reason the certificate of conformity could become invalid, the importation (introduction into circulation) of medical devices should be suspended;
4. Initiate the transfer of the certificate to another conformity assessment body.

NB! Transfer of the certificate to another conformity assessment body can be carried out in several ways, including that one without transferring a set of previously evaluated documentation. During the transfer process, it is also possible to move from audits to recognition procedure, expand the scope of medical devices, etc.

2. Technical regulations with which certain medical devices must comply.
By applying a conformity mark to the medical device, Manufacturer or its Authorised Representative assumes responsibility for compliance with the requirements of all applicable Technical Regulations. Besides the specialized "medical" regulations (TR 753, 754 and 755), other regulations may also be applied to medical devices.

Technical regulations on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) approved by Resolution No. 139 of the CMU dated March 10, 2017 are mandatory for:

- Electronic and electrical medical devices from January 1, 2018;
- Electronic and electrical medical devices for in vitro diagnostics from July 22, 2018.

Technical regulation of legally regulated measuring instruments approved by Resolution No. 94 of the CMU dated January 13, 2016, is mandatory from September 4, 2016, for medical DEVICES and medical devices for in vitro diagnostics specified in Appendix 1 to the regulation.

Technical regulation on radio equipment approved by Resolution No. 355 of the CMU dated May 24, 2017, entered into force on April 1, 2018, and is mandatory applied to the medical devices containing radiocommunication modules (GSM, Wi-Fi, Bluetooth, etc.).

Please pay attention that the medical devices which are subject of several Technical Regulations:

- must undergo conformity assessment procedures stipulated by all Technical Regulations prior to introduction of medical devices into circulation;
- are introduced into circulation with a single Declaration of Conformity (may be in the form of a "dossier");
- can have mandatory special requirements for labeling (e.g., an indication of the importer, additional metrological labeling, etc.).

3. Mandatory requirements for the labeling of medical devices with SI units.

We remind you that Order No. 914 of the Ministry of Economic Development dated August 4, 2015, establishes the mandatory requirements for labeling with SI units for the products introduced into circulation starting from January 1, 2019, including medical devices and medical products for in vitro diagnostics.

On the labeling of products represented in the Ukrainian market, the international designation of measuring units (with the use of the letters of the Latin or Greek alphabet) should be used. However, the Ukrainian designation of measuring units (with the use of the letters of the Ukrainian alphabet) can also be applied on the labeling.

Example of labeling with SI units:

100 ml

or

100 ml (мл)

4. List of EU notified bodies that signed Agreements on recongnition of confomity assessment results.

According to Article 45 of the Law of Ukraine "On Technical Regulations and Conformity Assessment", the designated conformity assessment body has the right to recognize the results of conformity assessment carried out beyond the territory of Ukraine under certain conditions. One of these conditions is the existence of an Agreement on Recognition of Conformity Assessment Results concluded between the Ukrainian and foreign authorities.

According to our information, at the end of October, the Agreements have been concluded with the following notification bodies:

1. TÜV SUD Product Service GmbH (0123)
2. TÜV Rheinland LGA Products GmbH (0197)
3. TÜV NORD Polska Sp. z o.o (2274)
4. BSI Assurance UK Limited (0086)
5. DEKRA Certification B.V. (0344)
6. DEKRA Certification GmbH (0124)
7. DQS Medizinprodukte GmbH (0297)
8. ITALCERT S.r.l. (0426)

9. Kiwa Cermet Italia S.p.a. (0476)
10. Kiwa Belgelendirme Hizmetleri A.Ş. (1984)
11. Lloyd's Register Quality Assurance (LRQA) (0088)
12. Eurofins product testing Italy s.r.l (0477)
13. Intertek Semko AB (0413)
14. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (0318)
15. Elektrotechnický zkušební ústav, s.p. (EZÚ) (1014)
16. Laboratoire national de métrologie et d'essais (LNE/G-MED) (0459)
17. SLG Prüf – und Zertifizierungs GmbH (0494)
18. Bureau Veritas Italia S.P.A. (1370)
19. Presafe Denmark A/S (0543)
20. Szutest Uygunluk Değerlendirme A.Ş. (2195)
21. MedCert Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH (MED-CERT) (0482)
22. National Evaluation Center of Quality and Technology in Health S.A. (EKAPTY) (0653)
23. Slovenian Institute of Quality and Metrology (SIQ) (1304)
24. UDEM Adriatic d.o.o. (2696)
25. IMQ Istituto Italiano del Marchio di Qualità S.P.A. (0051)
26. MDC medical device certification GmbH (0483)

Thus, the Agreements on Recognition have been already concluded with half (26 of 52) of the notified bodies designated for Directive 93/42/EEC. This is a significant achievement that allows to pass high-quality medical devices through a national procedure in a simplified way.

5. We invite you to take part in the events in which specialists of Cratia company will be the speakers:

Topic: **Building of effective protection against gray import and counterfeit products**
About 30-40% of medical devices in Ukraine are counterfeit. This causes significant official distributors' financial losses and manufacturers' image losses. There are many different ways by which falsified products enter into the market and find a buyer. We will talk about effective protection tools at different steps: import, wholesale, retail and hospital sales.
Date: December 6, Tuesday
Duration: 4 hours
Organizer: Association of Market Operators of Medical Devices (www.amomd.com)

For pre-registration, please contact us by e-mail education@cratia.ua