Designated conformity assessment body for medical devices and personal protective equipment

UKRAINIAN SCIENTIFIC INSTITUTE OF CERTIFICATION

www.uni-cert.ua
The Ukrainian Scientific Institute of Certification (Uni-Cert) is a designated body for conformity assessment of products and certification of quality management systems, has its own testing laboratory and training center.

Our solutions and services provide an independent assessment of product quality and safety, increase efficiency and increase trust. Our modern and competent approach to the processes and responsibilities, the focus on the European vector of Ukraine’s development is the key to the presence on the national market of the most high-tech products of the world’s leading manufacturers.

Our team is carefully selected from experts in various fields, for whom the conditions for continuous development and training are created both in Ukraine and among European market leaders. Our customers varies from the world's largest industry leaders to small national manufacturers.

To meet the requirements of the EU-Ukraine Association, we are constantly developing international cooperation and have concluded 27 Agreements with notified EU bodies.
**Company established**
Focus on assessment and development of regulatory documents for medicines and medical devices

**22.03.2010**

**August 2016**
- The 100th certificate was issued and the 100th audit was conducted

**September 2016**
- Designation by order of Ministry of Economy as conformity assessment body for medical devices and devices for in-vitro diagnostics. Identification number - UA.TR.116
- NAAU accreditation according to ISO/IEC 17021-1 and ISO/IEC 17025

**November 2015**
- First recognition agreement signed (TÜV SÜD)

**September 2015**
- Joined the Association of Medical Device Market Operators (AMOMD)

**February 2018**
- Training at Lloyd’s Register Quality Assurance (LRQA) (UK) on MDR and IVDR

**March 2017**
- Extension of scope of accreditation for ISO/IEC 17065 for personal protective equipment

**January 2017**
- NAAU granted accreditation for testing laboratory to ISO/IEC 17025

**March 2015**
- The 500th conformity certificate

**December 2015**
- NAAU accreditation according to ISO/IEC 17021-1 and ISO/IEC 17065

**February 2017**
- The 1000th audit was conducted

**End 2019**
- Extension of scope of accreditation to ISO/IEC 17021-1 for QMS certification according to ISO 22000

**August 2016**
- Extension of scope of accreditation for ISO/IEC 17065 for personal protective equipment

**January 2018**
- Joined the American Chamber of Commerce (ACC) in Ukraine

**December 2016**
- The 500th conformity certificate

**March 2017**
- NAAU granted accreditation for testing laboratory to ISO/IEC 17025

**December 2019**
- Joined the European Business Association (EBA)

**April 2020**
- Extension of scope of accreditation for ISO/IEC 17065 for electrical equipment

**End 2019**
- Extension of scope of accreditation for ISO/IEC 17065 for personal protective equipment

**Beginning 2020**
- Extension of scope of accreditation to ISO/IEC 17065 for electrical equipment

**Middle 2019**
- Introduction of a remote audit technique according to the requirements of IAF ID 3 and IAF MD 4
MAIN ACTIVITIES

**Product certification** is performed according to the accreditation certificate of National Accreditation Agency of Ukraine (NAAU, associate member of EA, member of ILAC and IAF) according to DSTU EN ISO/IEC 17065:2014 and designation of the Ministry of Economy in the following areas:

- medical devices;
- medical devices for in-vitro diagnostics;
- personal protective equipment.

**Quality management system certification** is performed according to the accreditation certificate DSTU EN ISO/IEC 17021–1:2017 and ISO/TS 22003: 2013 in the following areas:

- ISO 9001 - Quality management systems. Requirements
- ISO 13485 - Medical devices. Quality management system. Regulatory requirements
- ISO 22000 - Food safety management systems. Requirements for any food chain organizations

**Product testing** is performed according to the accreditation certificate DSTU ISO/IEC 17025:2017 for 167 parameters according to 23 national standards for:

- medical devices;
- medical devices for in vitro diagnostics;
- active implantable medical devices;
- personal protective equipment.
NATIONAL ACCREDITATION AGENCY OF UKRAINE
certifies our competence in accordance with the requirements of:

DSTU EN ISO/IEC 17021–1:2017
ISO/TS 22003:2013

DSTU EN ISO/IEC 17065:2014

DSTU ISO/IEC 17025:2017
UNI-CERT is accredited by the National Accreditation Agency of Ukraine in accordance with the requirements of **DSTU EN ISO/IEC 17065:2014** and designated by the Ministry of Economic Development of Ukraine to perform conformity assessment according to the Technical Regulations:

- **for medical devices** (Decree № 753);
- **for medical devices for in-vitro diagnostic** (Decree № 753);
- **for personal protective equipment** (Decree № 761);
The number of audits conducted in 35 countries, which resulted in the issuance of more than 1,000 product certificates:

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<tr>
<th>Year</th>
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<tr>
<td>2015</td>
<td>6</td>
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<td>2018</td>
<td>295</td>
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<td>2019</td>
<td>335</td>
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<td>2020*</td>
<td>238</td>
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(*first 9 months under global quarantine)
LANGUAGES OF AUDIT AND DOCUMENTS ASSESSMENT

We speak English, German, Polish, Slovak, Vietnamese, Russian
CERTIFICATION OF MANAGEMENT SYSTEMS


We have a positive experience of cooperation with Ukrainian and foreign bodies, in accordance with the international certification systems **ISO 9001,** **ISO 13485,** **ISO 14001,** **ISO 22000,** **ISO 45001,** **OHSAS 18001.** Our auditors are regularly trained and competent in national and international bodies, as evidenced by the relevant certificates.

> 40 certificates issued by the conformity assessment body UNI-CERT
PRODUCT TESTING

The accreditation of testing laboratories in Ukraine according to DSTU ISO/IEC 17025:2017 is an integral part of the recognition procedure of the testing results these laboratories carry out (International Laboratory Accreditation Cooperation (ILAC)).

The National Accreditation Agency of Ukraine confirmed the technical competence of the UNI-CERT Testing Laboratory for DSTU ISO/IEC 17025:2017 "General Requirements for the Competence of Testing and Calibration Laboratories". This indicates that the laboratory is able to provide accurate, reliable and reproducible product testing results and to fulfill applicant orders in a timely and complete manner.

Our laboratory has modern testing equipment that allows to study the characteristics of medical devices and personal protective equipment according to 23 local standards and 167 parameters.
INTERNATIONAL COOPERATION
with European notified bodies and laboratories

Articles 55 and 56 of the Association Agreement between Ukraine and the European Union as of 30 November 2015 encourage cooperation between organizations responsible for metrology, standardization, testing, market surveillance, certification and accreditation for the gradual approximation of Ukraine's technical regulation system to the EU.

The Ukrainian Scientific Institute of Certification has signed 27 agreements with EU notified 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. TÜV NORD CERT GmbH (0044)
5. BSI Assurance UK Limited (0086)
6. BSI Group The Netherlands B.V. (2797)
7. DEKRA Certification B.V. (0344)
8. DEKRA Certification GmbH (0124)
9. DQS Medizinprodukte GmbH (0297)
10. ITALCERT S.r.l. (0426)
13. Lloyd’s Register Quality Assurance (LRQA) (0088)
14. Eurofins product testing Italy s.r.l (0477)
15. Intertek Semko AB (0413)
17. Elektrotechnický zkušební ústav, s.p. (EZÚ) (1014)
18. GMED (0459)
19. SLG Prüf – und Zertifizierungs GmbH (0494)
20. Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (0318)
21. Presafe Denmark A/S (0543)
22. Szutest Uygunluk Değerlendirme A.Ş. (2195)
23. IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. (0051)
24. UL INTERNATIONAL (UK) LTD (0843)
25. RISE Research Institutes of Sweden AB (0402)
26. ICIM S.p.A. (0425)
27. CE Certiso Orvos- és Kórháziotechnikai Ellenőrző és Tanúsító Kft. (2409)

These agreements allow the recognition of the results (protocols) of European audits in accordance with Article 45 of the Law "On Technical Regulations and Conformity Assessment", which makes the conformity procedure more transparent and cost-effective. It also enhance the international cooperation in technical regulation, provides knowledge and experience from European colleagues and partners, and promotes the reforms required for the ACAA Agreement.
Our employees carry out their duties with enthusiasm and a responsible attitude. We encourage new ideas and always welcome those who challenge the working routine.
Continuous training of our team and customer specialists is the key to our leadership in the Ukrainian market. UNI-CERT training center held more than 150 educational events in various formats, from small groups for training in the "club format" to full-fledged conferences with representatives of state regulatory authorities.

The best specialists regularly act as experts at all major events of professional and public organizations, are the authors of more than 20 publications for major industry information resources.
Our Principles

Independence
The notified body is independent and impartial; its decisions are based solely on objective evidence of conformity.

Confidentiality
The notified body observes confidentiality of any proprietary information of the client.

Responsiveness to complaints
The notified body ensures that each and every complaint is handled in accordance with the established procedures, thus protecting its clients and applicants against errors.

Competence
The personnel involved in the conformity assessment process are equipped with appropriate qualification, expertise and professional experience.

Openness
The notified body provides the interested parties with access to information about its audit process, conformity assessment, its status, and to non-confidential information about the conclusions of specific conformity assessments.

Responsibility
The responsibility for conformity with the requirements rests with the client. The notified body has the responsibility to carry out the unbiased assessment of evidence of conformity.
ACTIVE PARTICIPATION IN GR

European Business Association (EBA)

American Chamber of Commerce (ACC) in Ukraine

Association of Market Operators of Medical Devices (AMOMD)
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