Message 103

Communication from the Commission - TRIS/(2024) 2042

Directive (EU) 2015/1535

Notification: 2024/0240/DE

Forwarding of the observations of a Member State (Poland) (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

MSG: 20242042.EN

1. MSG 103 IND 2024 0240 DE EN 05-08-2024 29-07-2024 PL COMMS 5.2 05-08-2024

2. Poland

3A. Ministerstwo Rozwoju i Technologii, Departament Obrotu Towarami Wrażliwymi i Bezpieczeństwa Technicznego, Plac Trzech Krzyży 3/5, 00-507 Warszawa, tel.: (+48) 22 411 93 94, e-mail: notyfikacjaPL@mrit.gov.pl

3B. Ministerstwo Rozwoju i Technologii, Departament Obrotu Towarami Wrażliwymi i Bezpieczeństwa Technicznego
oraz
Polskie Centrum Akredytacji

4. 2024/0240/DE - S00S - HEALTH, MEDICAL EQUIPMENT

5. article 5, paragraph 2, of Directive (EU) 2015/1535

6. Regarding notification: 2024/0240/DE; Health IT Interoperability Governance Regulation (GIGV)

Insofar as Germany intends to entrust the “Competence Centre for Interoperability in Healthcare (KIG) with the task of accrediting conformity assessment bodies, the draft law clearly violates EU law contained in Regulation (EC) 765/2008.

According to Article 4(1) and recital 15 of Regulation (EC) 765/2008, each Member State shall appoint a single national accreditation body. Currently, the national accreditation body in Germany is DAkkS Deutsche Akkreditierungsstelle GmbH. The accreditation is intended to serve as the ‘last level of control in the conformity assessment chain’ exercising public authority (recitals 15 and 19). The stabilisation of accreditation as the authoritative and therefore last level of control of conformity assessment activities from the point of view of technical competence is the cornerstone of the European accreditation policy.

All national accreditation bodies in the Member States are members of the European co-operation for Accreditation (EA). Implemented and managed within the EA, a robust, uniform and transparent peer evaluation system in accordance with Regulation (EC) 765/2008 ensures that all Member States have confidence in the activities of their national accreditation bodies and in the conformity assessment results achieved by the accredited conformity assessment bodies. In this situation, the established Centre of Competence would not be subject to this system.

With single national accreditation body as a member of EA, uniform application of accreditation requirements is ensured, which is crucial to maintain consistency and harmonisation across the EU. This helps to create a level playing field for businesses and conformity assessment bodies (CABs), avoiding discrepancies in accreditation practices between Member States.

For businesses and conformity assessment bodies, working with one, single accreditation body per country ensures

transparency and simplicity. It eliminates ambiguity as to which body to approach for accreditation, thereby facilitating access to accreditation services.

In particular, the following provisions of the GIGV Regulation are in conflict with EU law:

Section 2. Competence Centre for interoperability in the healthcare system
„9. examination of the professional and organisational capacity of the applicants to carry out a conformity assessment procedure in accordance with point 8 in conjunction with Section 13 by means of an accreditation procedure in accordance with Section 12 and continuous monitoring of compliance with the relevant requirements,,"

Section 12. Accreditation procedures
(43) Upon application in text form, the Competence Centre shall verify the professional qualification of the applicant to carry out procedures for assessing the conformity of information technology systems in accordance with Section 13.
(44) To this end the Competence Centre may require the applicant and their staff responsible for the management and performance of specialist tasks to provide the information and other assistance necessary for the assessment and monitoring of professional qualification, in particular to submit the relevant documents.
(45) In the Rules of Procedure, the Competence Centre shall define the professional and organisational requirements to be verified in accordance with paragraphs 1 and 2 and define the verification method to be applied.
(46) If evidence of professional qualification is provided, the Competence Centre shall provide the conformity assessment body with a corresponding accreditation certificate (accredited body). The Competence Centre shall publish the accredited bodies with an identification number on the platform in accordance with Section 6. The accreditation shall be granted for an appropriate period of time and subject to conditions.
(47) The Competence Centre shall monitor the accredited bodies. If the Competence Centre determines that an accredited body no longer has the necessary qualifications in accordance with paragraphs 1 und 3, has seriously violated an obligation pursuant to parapraph 4, sentence 3 or its other obligations, the Competence Centre shall, within a reasonable period of time, take all appropriate measure to restrict, suspend or withdraw the accreditation; the Competence Centre may also revoke accreditations.
(48) In the Rules of Procedure, the Competence Centre shall establish a procedure in accordance with Section 17 for how to deal with appeals against decisions of the Competence Centre in accordance with paragraphs 4 und 5.
(49) A conformity assessment body may not carry out a conformity assessment in accordance with Section 13 in conjunction with Section 387 of Book V of the Social Code, without accreditation in accordance with this provision.

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European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu