

Standardization and conformity assessment as tools for enter of innovative products to the market

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DAkkS in brief

- DAkkS is **Germany's national accreditation body**
- **Legal mandate:** accreditation of CABs
- Operational since 1st January 2010
- DAkkS is subject to supervision by the **Federal Government**
- Delegation of **public service tasks** by entrustment
- DAkkS is operating on a **non-profit basis**

Accreditation activities of DAkkS

Laboratories	Testing and Calibration Laboratories ISO/IEC 17025
	Medical Laboratories ISO 15189
Inspection Bodies	ISO/IEC 17020
Certification Bodies	for Persons ISO/IEC 17024
	for Management Systems ISO/IEC 17021
	for Products ISO/IEC 17065 (old: EN 45011)
Validation and Verification Bodies	ISO 14065
Providers of Proficiency Tests	ISO/IEC 17043
Producers of Reference Materials	ISO Guide 34 (17034)

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Accreditation in the EU

- performed by NABs appointed by Member States as required by EU Regulation 765/2008
- Regulated area:
 - accreditation required by law
 - qualifies certain products/services which can be put onto the market only after undergoing conformity assessment against the applicable standards (notification)
- Voluntary area:
 - no specific legislation
 - CABs seek accreditation to provide the market with an impartial attestation of their competence

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Accreditation and notification

ISO standards
(17000 series)

1. step:
**accreditation
from DAkkS**

proof of competence
(with regard to technical
abilities)

2. step:
**notification from
national authority**

legal authorization

DE: 208 NBs in total

**CAB offers
conformity
assessment
in this area to
the market**

Strengthening of Accreditation

Decision No 768/2008/EC

- (38) ... Since **accreditation** is an essential means of verifying the competence of conformity assessment bodies, its use should also be **encouraged for the purposes of notification.**

(DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a common framework for the marketing of products)

Overview – Innovative Technologies

- IEC 62443 Industrial Automation and Control Systems Security
- Critical Infrastructures (Energy distribution) – Energy Act
- Code of PLM Openness (CPO) – Realizing IoT
- Trust Services – EU Regulation 910/2014 - eIDAS
electr. IDentification And trust Service for el. Transactions
- Financial Services – Directive 2014/92/EU
- General Data Protection Regulation – Regulation 2016/679