



# Behind the CE Mark: The Hidden Mechanics of EU Notification

What Every Conformity Assessment Professional Must Know!

By Dr. George Anastasopoulos  
PJLA, Technical & Intl. Business Development Manager



# About PJLA

## **Perry Johnson Laboratory Accreditation, Inc. (PJLA)**

Established in 1999 by Mr. Perry L. Johnson

Headquartered in Troy, Michigan.

More than 2200 accreditations globally in 32 countries.

## **Perry Johnson Laboratory Accreditation NP, Inc. (PJLANP)**

Michigan nonprofit organization established in 2016.



Perry L. Johnson

Member and signatory of APAC, ILAC MRAs



# PJLA's Global Network



*Perry Johnson Laboratory Accreditation, Inc.*

# PJLA Accreditation Programs

## ISO/IEC 17025

### Testing/Calibration Labs

- FCC OET Equipment Authorization
- FDA ASCA
- ENERGY STAR
- Cannabis Testing
- Hemp Testing
- Horseracing Laboratories Program
- CPSC
- AS6171A Testing
- Food, Feeds, and Pharmaceutical:  
*AOAC, AAFCO, LAAF*
- Environmental Testing: *TNI-NEFAP, DoD ELAP, DOECAP-AP, EPA NLLAP*  
TNI-EL: *MNELAP, CA ELAP, LELAP*

**ISO/IEC 17020** – Inspection Bodies

**ISO/IEC 17065** – Product Certification Bodies

**ISO/IEC 17043** – Proficiency Testing Providers

**ISO 17034** – Reference Material Producers

**ISO 15189** – Medical Laboratories

**ISO/IEC 17024** – Personnel Certification Bodies

**ASTM E2659**– Training Providers



# Introduction–Why This Webinar Matters

Provide a complete, regulator-aligned explanation of EU Notification and CE Marking

- Address all questions faced by Conformity Assessment Bodies (CABs)
- Clarify the roles of manufacturers, CABs, accreditation bodies, and authorities
- Inform about EU regulatory requirements and related accreditation/notification assessments
- Covering Key Questions on Notification, CE Marking, Accreditation, Non-EU Bodies, MRAs & Regulation (EC) No 765/2008



# WHY do we care?

Knowing the mechanics behind notification and CE marking is a business advantage:

- It reduces regulatory risk,
- prevents costly market entry errors,
- speeds access to the EU market,
- strengthens credibility with clients, and
- enables professionals to offer higher-value advisory services by navigating directives, modules, and Notified Body requirements with precision and confidence.



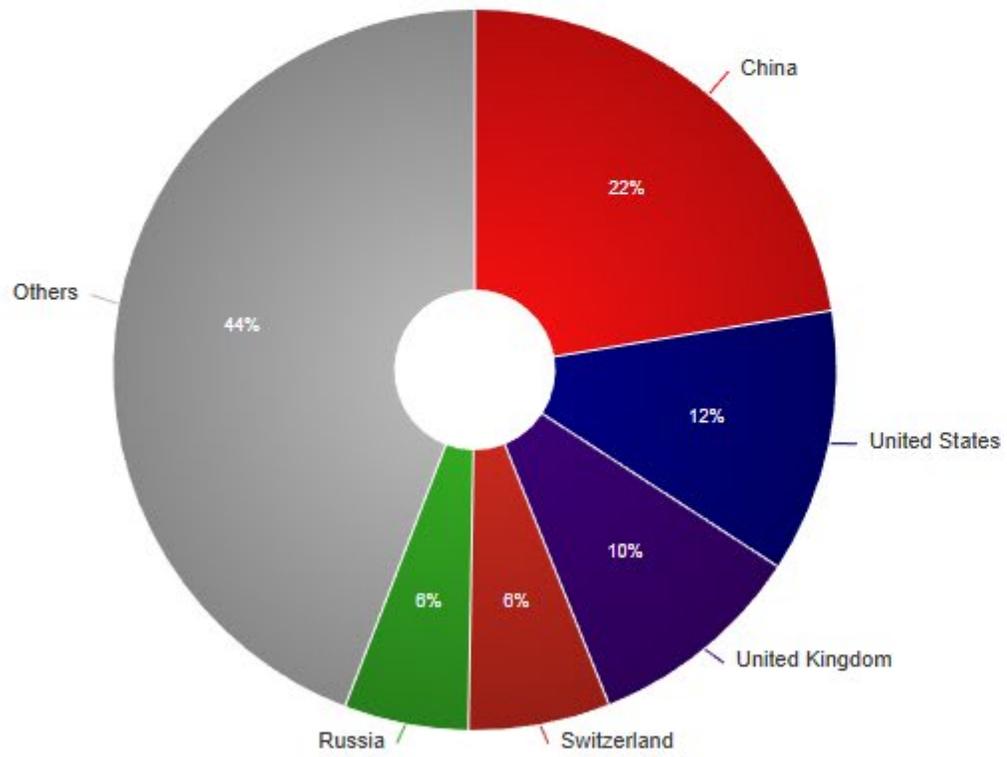
# WHY do we care?

Trade in goods by top 5 partners, European Union, 2020

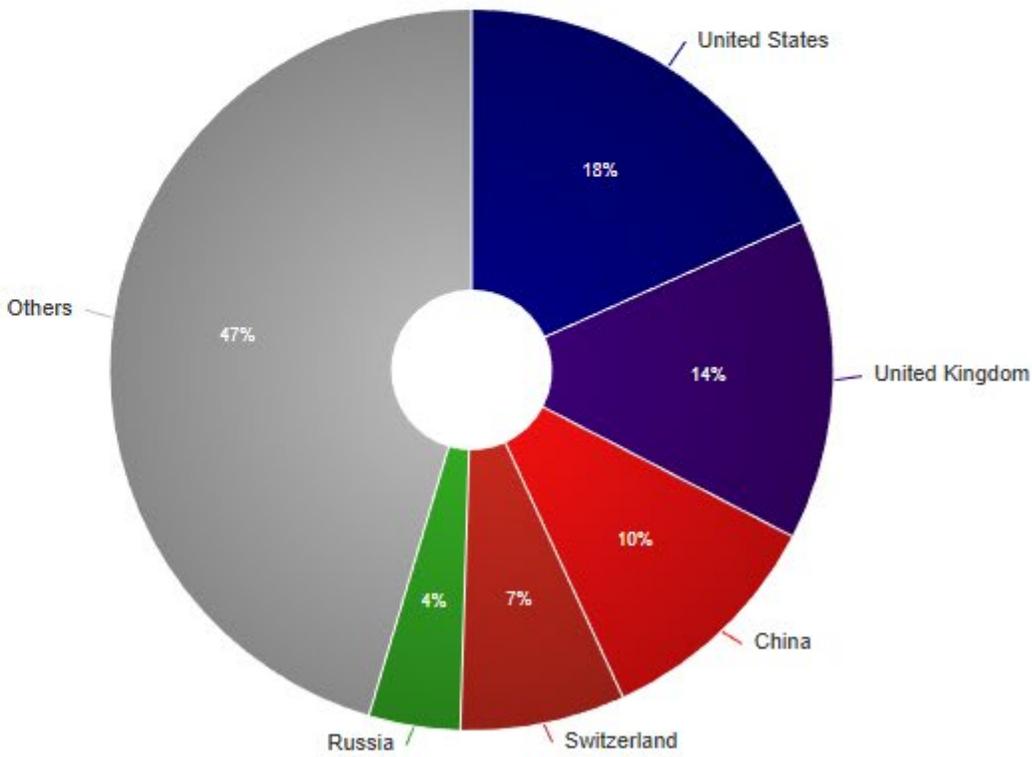
(in %)

 European Union ▼

Imports



Exports



# What Is Notification in the EU?

Notification is a formal act by an EU Member State that:

- Confirms designation of a Conformity Assessment Body (CAB)
- It informs the European Commission and other Member States about a CABs compliance to EU requirements
- Grants legal authority to CAB to perform regulated conformity assessments

Notification is published in the NANDO (New Approach Notified and Designated Organizations) database



# Why Notification in the EU?

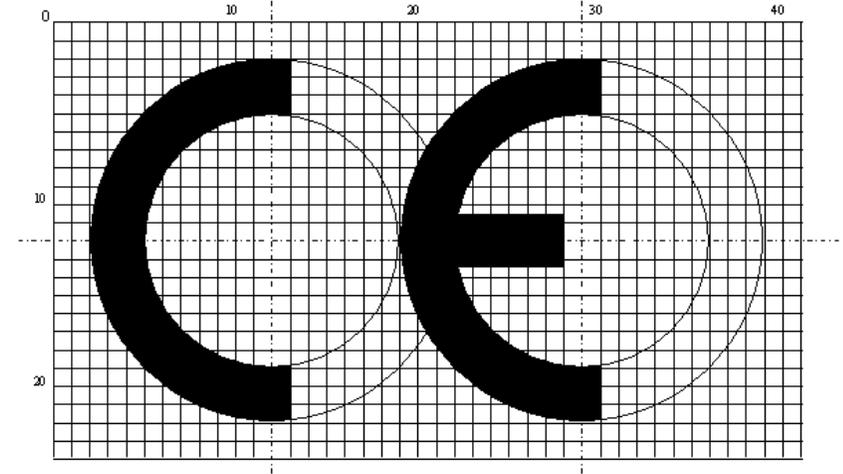
- Products requiring third-party assessment cannot be sold in the EU without CE marking
- CE marking in many case needs a notified body's certificate.
- Only notified bodies are legally authorized to perform conformity assessment for certain CE-marked products.
- Notification ensures the CAB is competent, accredited, and approved by an EU authority.
- Notification protects the EU market from unsafe or non-compliant products.
- It guarantees trust, oversight, and harmonized acceptance across all EU Member States.



# What Is CE Marking?

CE Marking is a legal marking required by EU harmonization legislation

- Indicates conformity with safety, health, and environmental requirements
- Represents manufacturer responsibility and legal accountability
- Not a quality mark, approval, or certification label



# Relationship Between Notification and CE Marking

## CE Marking may require third-party conformity assessment

- Only notified bodies may perform regulated third-party tasks
- Notification enables legal involvement in CE assessment routes
- Without notification, CE-related activities have no legal standing

# Who Can Be Notified?

- 
- **Testing laboratories,**
  - **Inspection bodies, and**
  - **Certification bodies**

- Must demonstrate competence, impartiality, and independence
- Must comply with applicable ISO/IEC standards
- Must meet sector-specific EU legislative requirements

# Who Provides Notification?

## Notification is issued by national authorities of EU Member States

- Authorities act under EU law and national implementing legislation
- They evaluate designation evidence before notifying
- The act of notification is sovereign and legal, not technical

*Each Member State shall establish or designate as national competent authorities at least one notifying authority and at least one market surveillance authority (per regulated product/service category)*

# Who Provides Notification?

- **Notifying Authorities:** These are governmental or designated bodies (e.g., ministries, agencies) in each Member State.
- **ABs** are generally **NOT** the official notifying authorities
- **National Accreditation Bodies (NABs):** These are organizations (one per country) that formally accredit CABs (testing labs, certification bodies) to confirm they meet technical standards (e.g., ISO/IEC 17025, 17065).

**Notification** is a legal decision made by national authorities, while

**Accreditation** provides the technical assessment verifying a body's competence.

**Exception:** In some cases, the NAB may be part of a larger, single administrative structure that serves as the Notifying Authority, or they may be authorized to act on behalf of the government.



# Role of Accreditation Bodies & Reg. (EC) No 765/2008

## Accreditation bodies assess technical competence of CABs

- They operate under Regulation (EC) No 765/2008
- Accreditation supports designation but is not notification
- Authorities typically rely on accreditation as primary evidence

## (EC) No 765/2008 establishes EU framework for accreditation and market surveillance

- Requires one national AB per Member State
- Defines accreditation as a public authority activity
- Ensures consistency and trust across the EU conformity system



# Process for Becoming a Notified Body (EU-Based)

## Obtain accreditation to applicable ISO/IEC standard

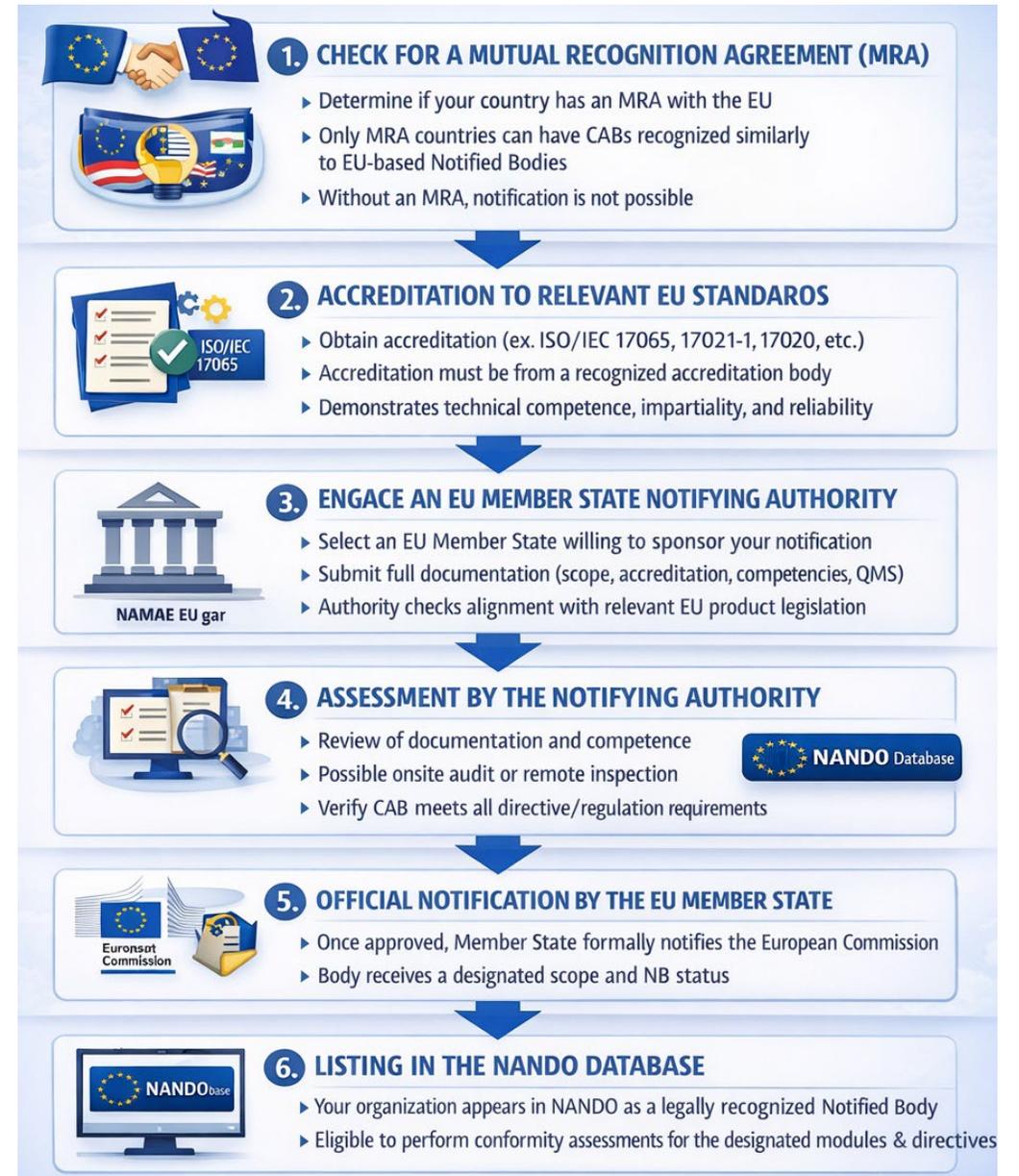
- Apply to the national notifying authority
- Undergo designation assessment by authority
- Formal notification to the European Commission
- Entry into NANDO database
- Monitoring



# Can a Non-EU Body Become Notified?

## Yes, under specific conditions

- Must operate in a country with MRA with EU
- Must meet identical technical and impartiality requirements
- Often requires EU legal presence or formal arrangements
- Subject to EU oversight and transparency obligations



# International Agreements under EU NANDO

## EU recognizes specific third countries under MRAs

- Agreements define scope and limitations of recognition
- MRA does not remove regulatory scrutiny or designation steps

| Country       | Comment   |
|---------------|---|
| Australia     | MRA   |
| Canada        | CETA  |
| Japan         | MRA   |
| New Zealand   | MRA   |
| Switzerland   | MRA and LTA (Directive 2008/57/EC by virtue of Decision 1/2013 and the EU-Switzerland Land Transport Agreement - LTA) |
| United States | MRA   |
| Turkey        | listed by virtue of Decision 2006/654/EC  |

# Examples of US-Based Notified Bodies

## Several US organizations are notified under EU MRAs

- Cover sectors such as EMC, radio, marine equipment
- Demonstrate feasibility of non-EU notification
- Subject to the same EU oversight rules
- NANDO link:

<https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>

| Body type | Body name  |
|-----------|--|
| NB 3042   | <a href="#">Compliance Testing, LLC</a>                                |
| NB 1925   | <a href="#">Compatible Electronics, Inc.</a>                           |
| NB 3052   | <a href="#">DERYCOM CERTIFICATION SERVICES, INC.</a>                   |
| NB 0982   | <a href="#">Element Materials Technology Washington DC</a>             |
| NB 2863   | <a href="#">Technology International, Inc.</a>                         |
| NB 0980   | <a href="#">Eurofins Electrical and Electronic Testing NA, Inc.</a>    |
| NB 0978   | <a href="#">Elite Electronic Engineering, Inc.</a>                     |
| NB 0981   | <a href="#">Element Materials Technology Portland - Evergreen Inc.</a> |
| NB 1313   | <a href="#">Bay Area Compliance Laboratories Corp.</a>                 |
| NB 1317   | <a href="#">Washington Laboratories, Ltd.</a>                          |
| NB 1588   | <a href="#">ACB, Inc.</a>  |
| NB 2799   | <a href="#">Vista Laboratories, Inc.</a>                               |
| NB 2907   | <a href="#">Sporton International (USA) Inc.</a>                       |
| NB 2200   | <a href="#">Bureau Veritas Consumer Products Services, Inc.</a>        |
| NB 2280   | <a href="#">MiCOM LABS</a>   |
| NB 1177   | <a href="#">IIA Lab Services, LLC</a>                                  |
| NB 0984   | <a href="#">UL Verification Services Inc.</a>                          |
| NB 2906   | <a href="#">SGS North America, Inc.</a>                                |
| NB 1408   | <a href="#">United States Coast Guard</a>                              |
| NB 0976   | <a href="#">CKC Certification Services, LLC</a>                        |



# International Branches of EU Notified Bodies

## Branches that operate under the parent body's notification:

- No need to follow above mentioned process
- Remain under supervision of the original notifying authority
- Still need to be assessed by the EU member state that oversees the parent notified body
- Formal recognition is still required



# CE Marking – Scope/Market Surveillance/Enforcement

## CE marking applies across multiple EU directives and regulations

- Covers sectors from toys and machinery to AI and cybersecurity
- Each legislation defines its own conformity assessment rules
- Not all products or services fall under CE marking

## Member States must operate effective market surveillance

- Authorities verify compliance after market placement
- Non-compliant products may be restricted or withdrawn
- Complements accreditation, notification, and CE marking

**CE marking is a legal declaration, not an approval**



# CE Marking categories

- Toy Safety - Directive 2009/48/EU
- Transportable pressure equipment - Directive 2010/35/EU
- Restriction of Hazardous Substances in Electrical and Electronic Equipment - Directive 2011/65/EU
- Construction products - Regulation (EU) No 305/2011
- Pyrotechnic Articles - Directive 2013/29/EU
- Recreational craft and personal watercraft - Directive 2013/53/EU
- Civil Explosives - Directive 2014/28/EU
- Simple Pressure Vessels - Directive 2014/29/EU
- Electromagnetic Compatibility - Directive 2014/30/EU
- Non-automatic Weighing Instruments - Directive 2014/31/EU
- Measuring Instruments - Directive 2014/32/EU
- Lifts - Directive 2014/33/EU
- ATEX - Directive 2014/34/EU
- Radio equipment - Directive 2014/53/EU
- Low Voltage - Directive 2014/35/EU
- Pressure equipment - Directive 2014/68/EU



# CE Marking categories

- Marine Equipment - Directive 2014/90/EU
- Cableway installations - Regulation (EU) 2016/424
- Personal protective equipment - Regulation (EU) 2016/425
- Gas appliances - Regulation (EU) 2016/426
- Medical devices - Regulation (EU) 2017/745
- In vitro diagnostic medical devices - Regulation (EU) 2017/746
- EU fertilising products – Regulation (EU) 2019/1009
- Drones - Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems
- Batteries - Regulation (EU) 2023/1542
- Machinery - Regulation (EU) 2023/1230 (replacing Directive 2006/42/EC)
- Ecodesign requirements for sustainable products - Regulation (EU) 2024/1781
- Artificial Intelligence Act - Regulation (EU) 2024/1689
- Cyber Resilience Act - Regulation (EU) 2024/2847
- Packaging and Packaging Waste - Regulation (EU) 2025/40



# Common Regulatory Errors

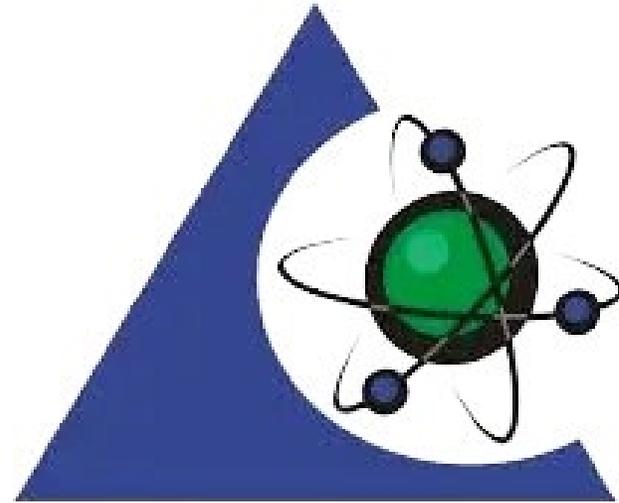
- Confusing accreditation with notification
- Incorrect classification (directive/regulation)
- Assuming CE marking is always self-declared
- Ignoring post-market surveillance obligations
- Misunderstanding the authority of notifying bodies
- Misassumption that US clearance is enough
- Lack of evidence of compliance with standards
- Inadequate Document Control
- Frequently updating regulations are ignored



# Thank You!

- Questions
- Discussion

[ganast@pjlabs.com](mailto:ganast@pjlabs.com)



**PJLA**  
**[pjlabs.com](http://pjlabs.com)**

