



Standards and Conformity Assessment Procedures

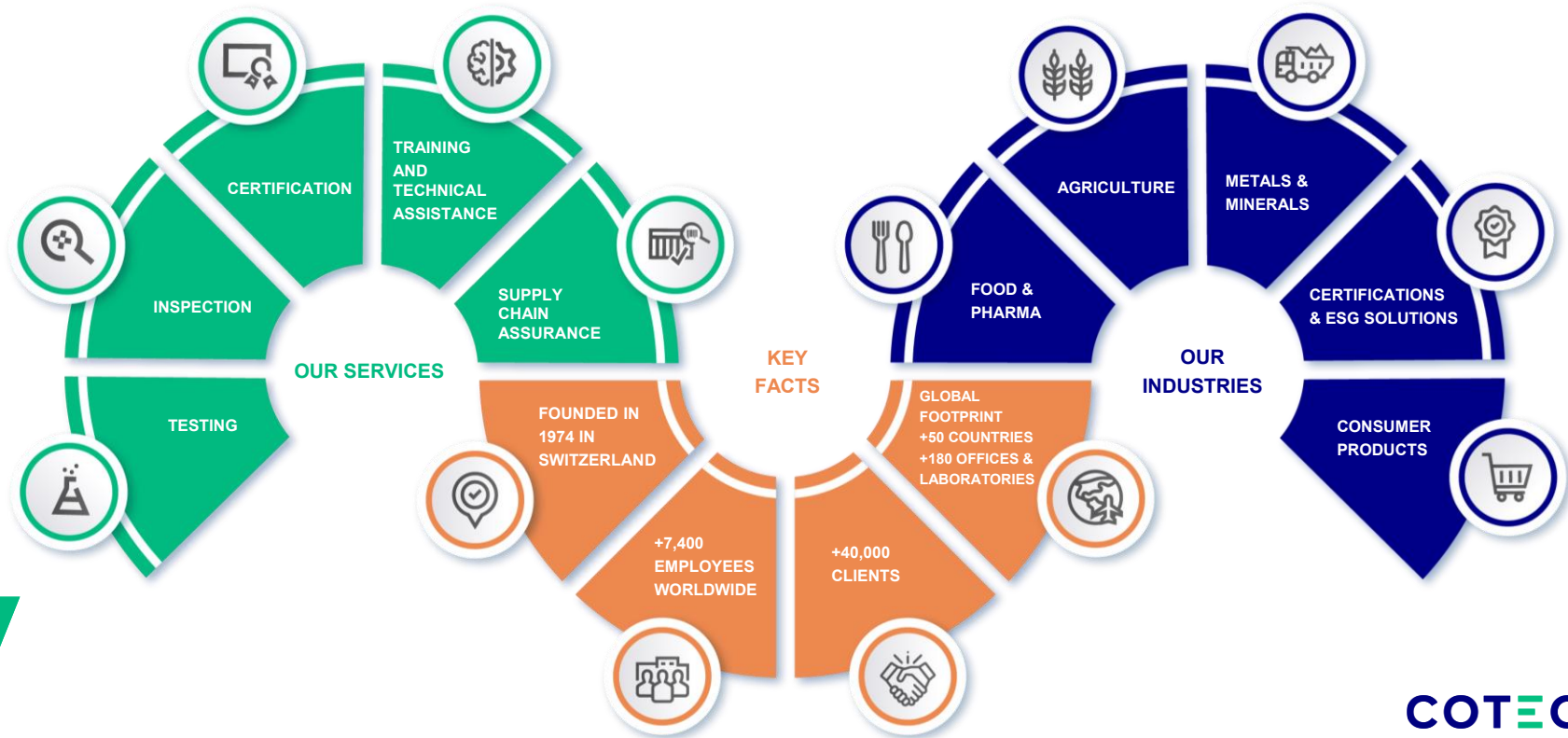
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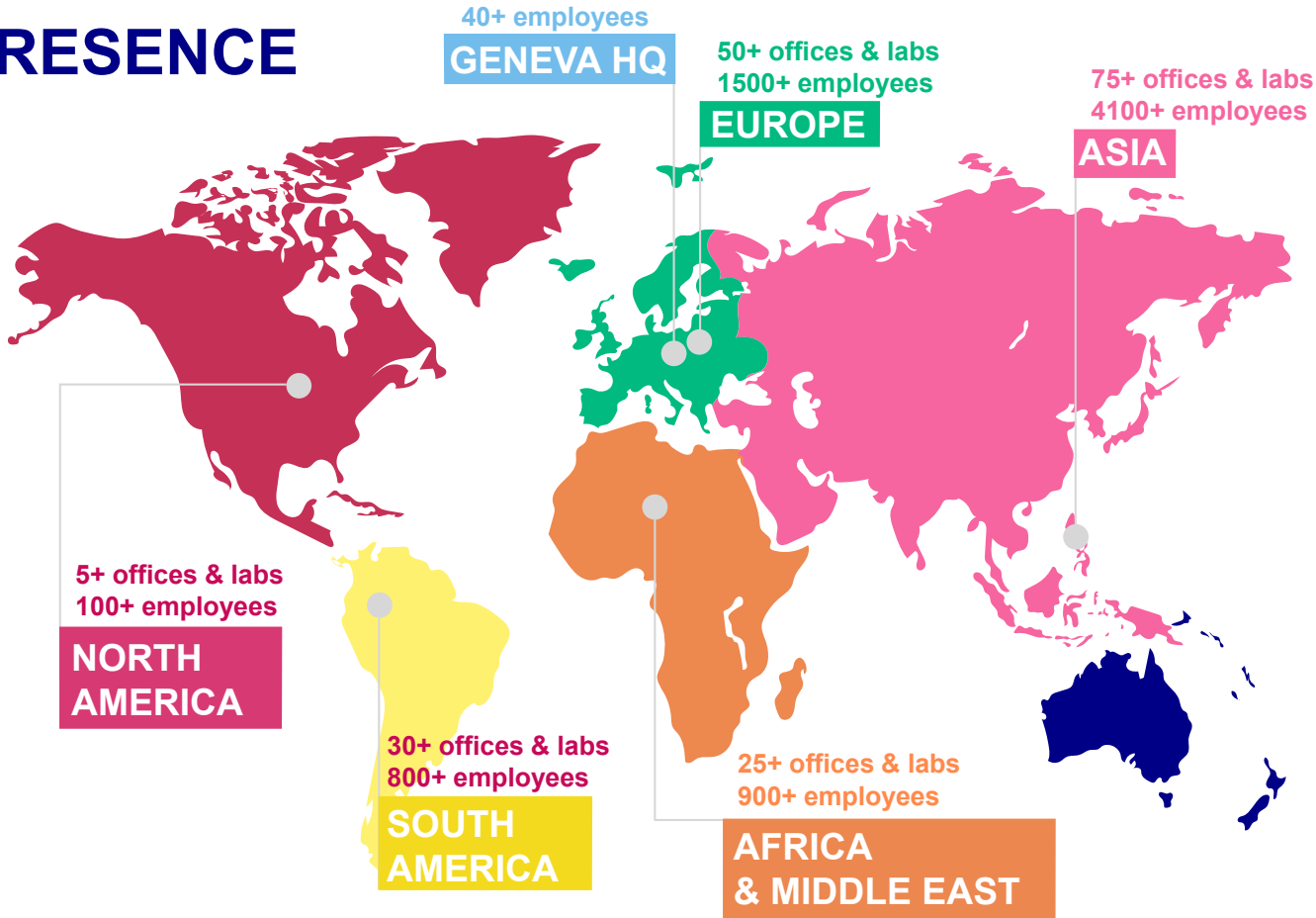
Testing Against Specific Standards as a Tool for Supporting Manufacturer's (Self) Declarations of Conformity to Purchaser Specifications or Government Regulations and Quality Assurance

Benefits and Challenges for SMEs

For over 50 years, we have been supporting agriculture, food and pharma, minerals and metals, and consumer products supply chains all over the world. We provide testing, inspection, and certification services to help our clients navigate evolving regulations, ensure product compliance, and support their sustainability journey.

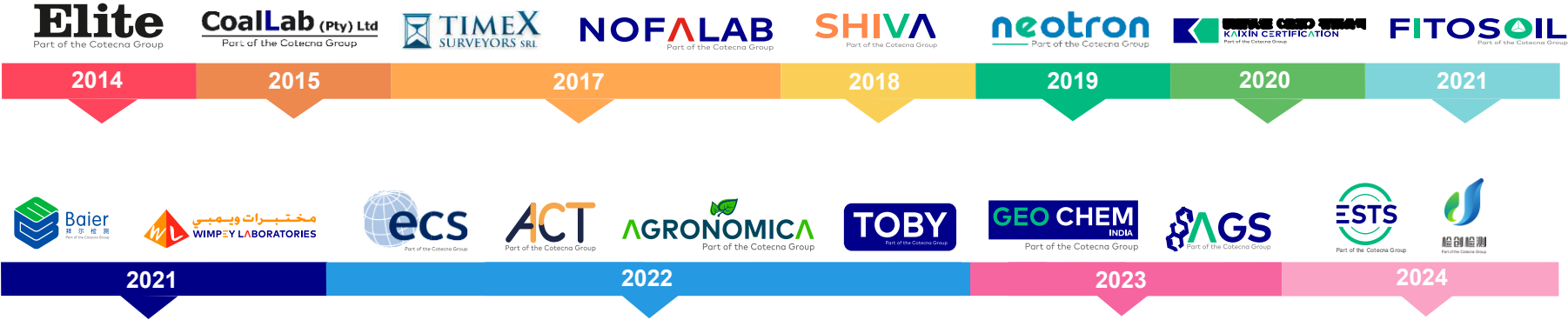


OUR PRESENCE



GROUP ACQUISITIONS

To expand our presence in key markets and major business sectors, Cotecna pursues strategic acquisitions of leading companies in analysis, inspection, and certification, with each acquisition adding expertise to our DNA.



Standards and Conformity Assessment

Standards

Documented guidelines that ensures safety, quality and efficiency

e.g. ARS, ISO, IEC. ASTM, EN, EAS etc

They matter because they ensure a standard level playing field and increases consistency, quality, efficiency for the market.

Conformity Assessment

The processes used to determine whether a product, service, system, or personnel meets specified standards, regulations, or technical requirements.

Types

First-party (self-declaration)

Second-party (customer audits)

Third-party (certification bodies)

These help verify compliance with safety, quality, environmental, and performance standards before products reach consumers or enter the market.

Testing



Testing

Testing is a critical conformity assessment procedure that verifies whether a product, service, or system meets established **standards, regulations, and safety requirements.**

Key/Essential Areas Testing for SMEs.

Performance testing - products function as advertised/ or declared. “A battery should perform as a battery etc”

Safety testing – Fitness for use, no malfunctions, no HSE concerns etc

Compliance testing – acceptability with regulatory authorities as per mandated regulated standards e.g. Import regimes on various jurisdictions.

Manufacturer's (Self) Declaration of Conformity (SDoC)

What is it? – is a formal statement by a manufacturer or supplier confirming that their product meets applicable regulatory, safety, and technical standards without requiring third-party certification.

The manufacturer has carried out sufficient testing to confirm compliance and typically supported by internal test reports, risk assessments, and technical documentation.

The manufacturer takes responsibility for compliance instead of an external certification body.

Examples of SDoC:

- a) CE Marking (Europe): Many low-risk electronic devices, such as laptops and household appliances, require an SDoC before being sold in the EU.
- b) In some cases, Class I medical devices (e.g., thermometers, bandages) can be self-declared compliant before entering the market.
- c) Vehicle manufacturers may provide an SDoC to confirm that their cars meet emission or safety standards.

Benefits of Self Declaration of Conformity (SDoC)

Faster market access

Reduced certification costs

Flexibility in compliance

Risks

Increased liability

Potential market barriers without third-party validation

Government Regulations & QC in brief

Many jurisdictions have regulations for compliance.

CE marking, FDA in the US, EMC compatibility for small electrical items
In Africa, Quality Marks for locally produced and Import Marks based on Standards under WTO/TBT arranged programs.

Important to SME to comply mainly for

- **Risk reduction and legal comfort,**
- **Product credibility,**
- **consumer acceptance & trust,**
- **advantage in cross border trade.**

Challenges SMEs face

- High testing and certification costs
- Complexity of multiple regulatory requirements
- Limited technical expertise and resources
- Need for continual updates to standards

Some ways to mitigate?

- Government support and funding programs
- Use of third-party consultants
- Collaboration with industry associations
- Adoption of scalable QA systems

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