TIC COUNCIL

THE INDEPENDENT VOICE OF TRUST

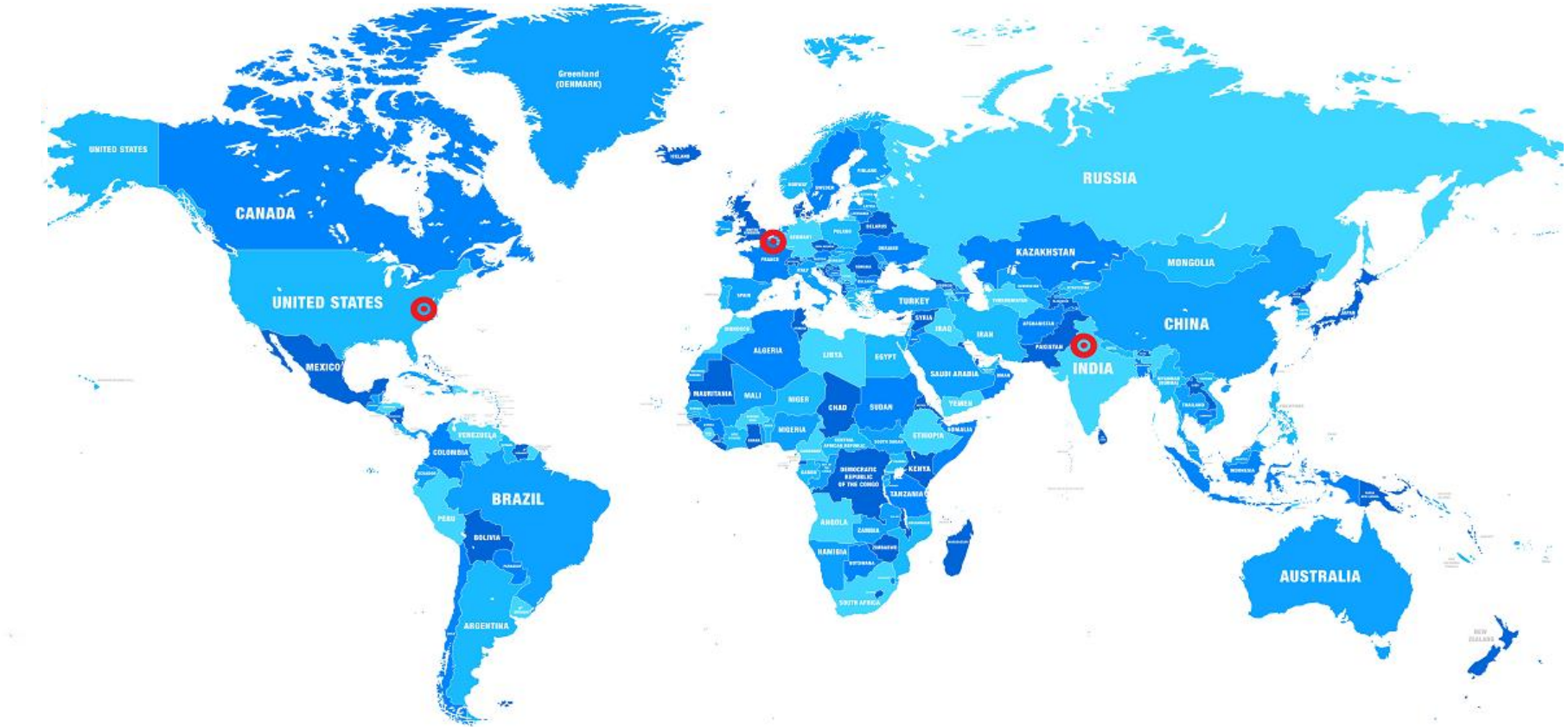
TIC Council – EUIPO Webinar
Non-conform imported PPEs, medical devices and fake certificates

28 May 2020

TIC Council

The Independent Voice of Trust

- Born from the merger of IFIA and CEOC
- ~90-member companies & organizations active in more than 160 countries (HQ mapped)
- TIC Council has its head office in Brussels. It also has an office in Washington and presence in India.



TIC Council Mission

As the voice of the global independent testing, inspection and certification industry, the TIC Council engages governments and key stakeholders to advocate for effective solutions that protect the public, support innovation and facilitate trade.

The TIC Council works with its members to promote best practices in safety, quality, health, ethics and sustainability.

Anti-Counterfeiting Committee

Certification industry members committed to stopping the worldwide proliferation of products bearing counterfeit certification marks that may endanger public health and safety by:

- Partnering and cooperation between key stakeholder – certification bodies, brand owners, law enforcement;
- Educating key stakeholders, including law enforcement (customs authorities), legislators, manufacturers and consumer organisations; and,
- Aligning and adhering to consistent principles as TIC industry in fighting counterfeiting.

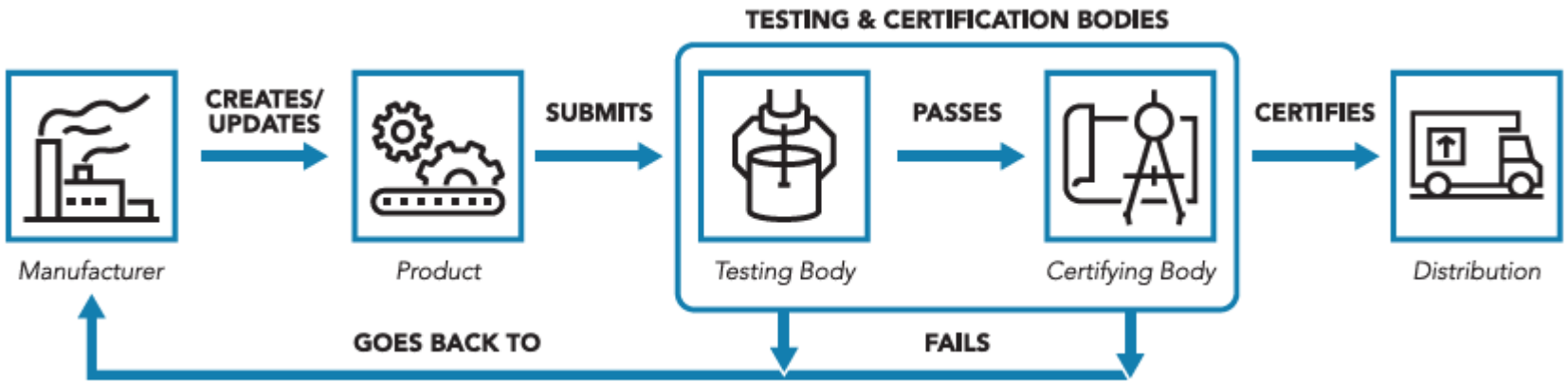
Certification Bodies and Product Certification

- TIC Council Members are Testing, Inspection and Certification Bodies which provide essential services related to testing, inspecting and certifying products.
  - *ISO/IEC 17065, The international standard for ensuring competence in organizations performing certification activities*

- Product Certification is the evaluation and confirmation by an independent third party that a representative product sample meets the requirements of applicable, published standard(s).

- Requirements may be related to safety, performance or quality assurance

- Product Certification may be voluntary or mandatory, depending on jurisdiction.



Two Types of Marks:
Certification Marks and Self-Declaration Marks

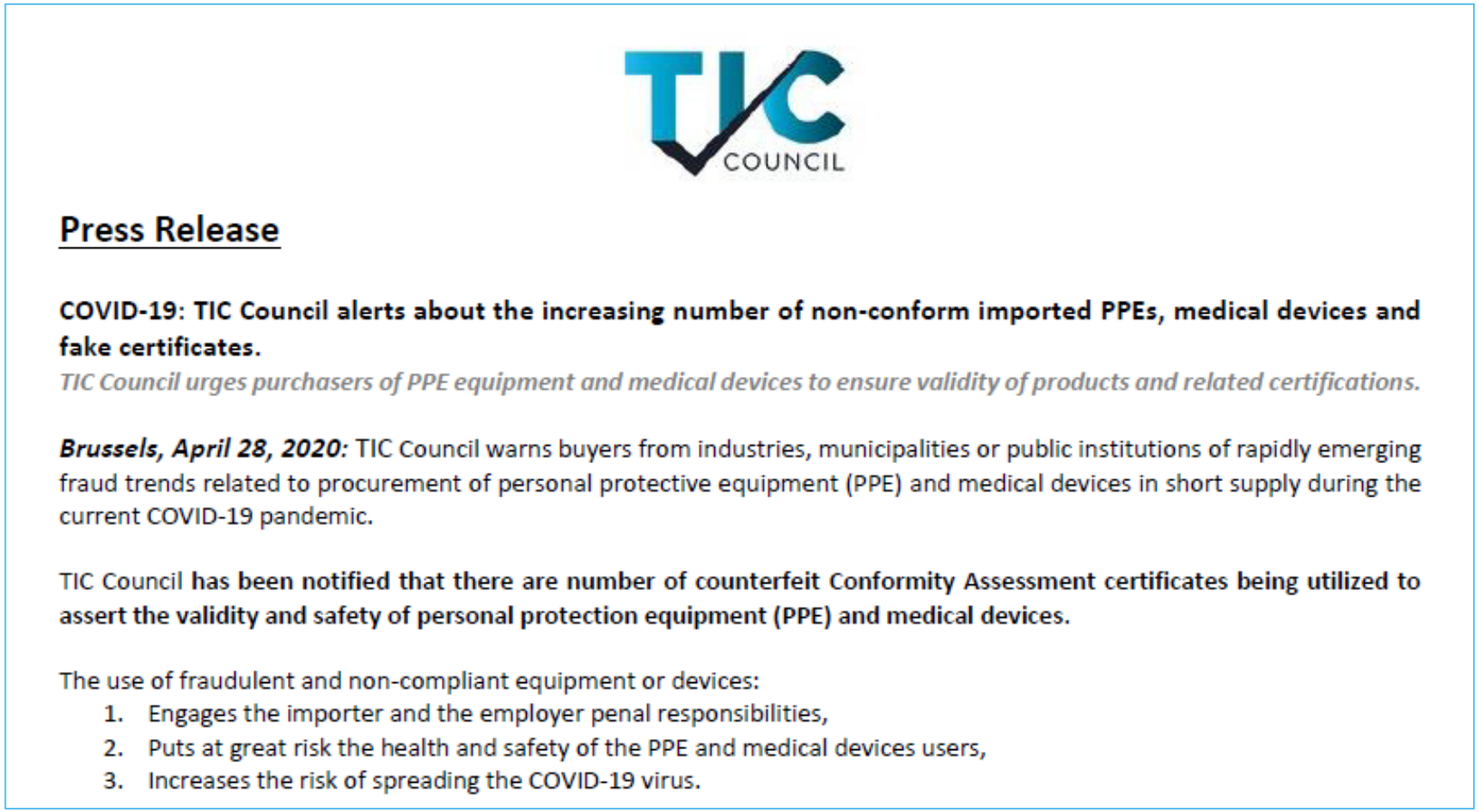
- A Certification Mark issued by a Certification Body indicates that a representative product sample was tested and met the requirements of a published standard. Additionally, the product is in a Certification Program which will have additional requirements such as an initial factory audit, and periodic inspection or testing activities which may include lot inspections.
- Certification Marks are owned by the Certification Body. The Certification Body grants authorization to use their Certification Mark to third parties. Certification Marks may not be used without authorization.
- CE Mark *with* a four (4) digit number indicates assessment by an independent third party.

Certification and Self-Declaration of the manufacturer

- Manufacturers may make a self-declaration that a product meets safety, performance or quality requirements

  - Indicated with the CE Marking (*no additional numbers*)
  - Does not require independent verification of compliance

Impact of COVID-19 Pandemic



Press Release

COVID-19: TIC Council alerts about the increasing number of non-conform imported PPEs, medical devices and fake certificates.

TIC Council urges purchasers of PPE equipment and medical devices to ensure validity of products and related certifications.

Brussels, April 28, 2020: TIC Council warns buyers from industries, municipalities or public institutions of rapidly emerging fraud trends related to procurement of personal protective equipment (PPE) and medical devices in short supply during the current COVID-19 pandemic.

TIC Council **has been notified that there are number of counterfeit Conformity Assessment certificates being utilized to assert the validity and safety of personal protection equipment (PPE) and medical devices.**

The use of fraudulent and non-compliant equipment or devices:

1. Engages the importer and the employer penal responsibilities,
2. Puts at great risk the health and safety of the PPE and medical devices users,
3. Increases the risk of spreading the COVID-19 virus.

https://www.tic-council.org/news-and-events/march-2019/covid-19-tic-council-alerts-about-increasing-number-non-conform-imported-ppes-medical-devices-and-fake-certificates

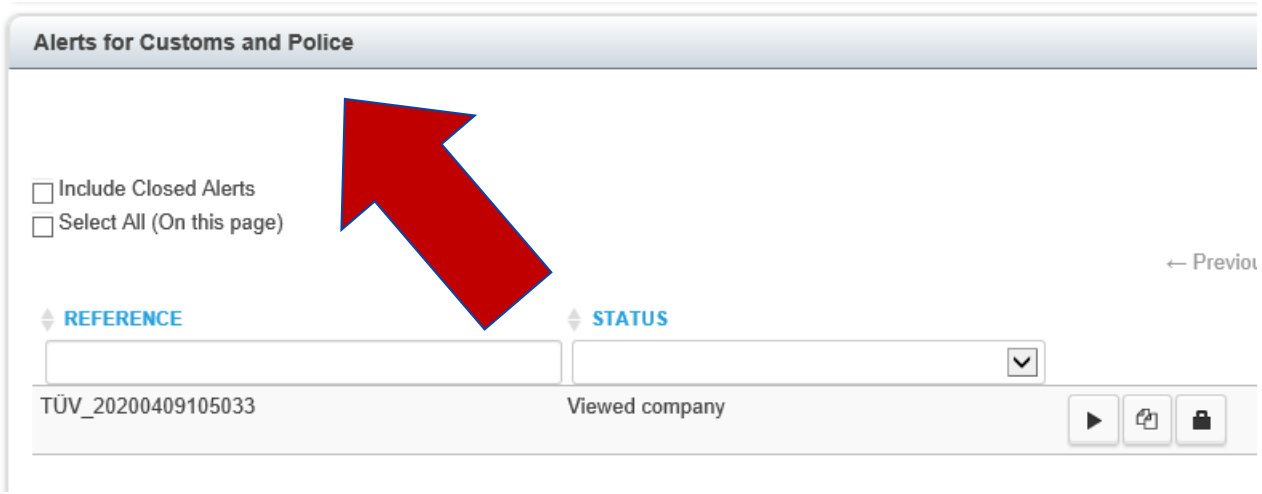
Counterfeit Certificates: Case Studies

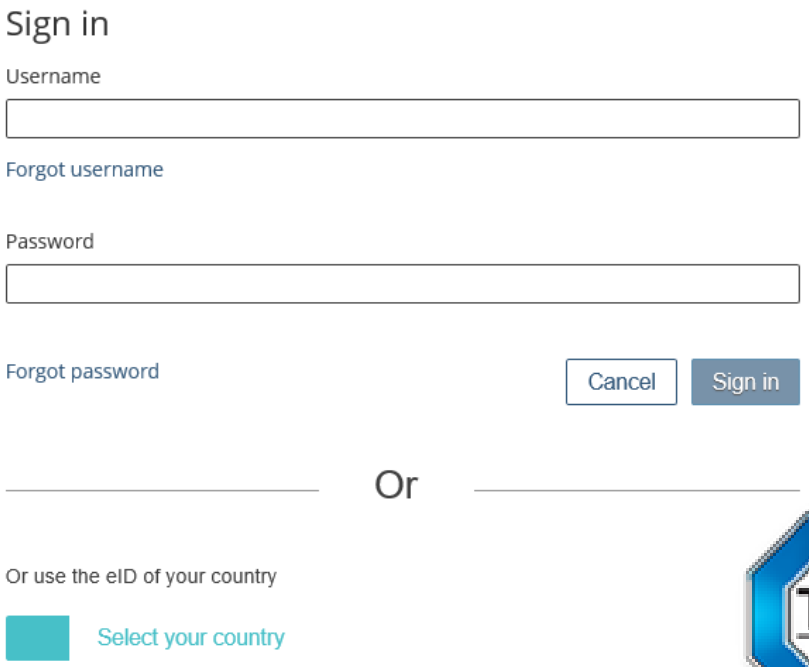
Case studies reviewing real incidents of counterfeit certificates were presented by:

EUIPO IP-Enforcement Portal for Communication with LEA‘s

IP ENFORCEMENT portal

Step into your IP Enforcement Community





Masks

PROTECT THE PATIENT

SURGICAL MASK

MEDICAL DEVICE (MD) DIRECTIVE

EN 14683:2019+AC:2019

TYPE I, II or IIR

SELF CERTIFICATION

CE

REGISTER YOUR PRODUCT AT THE NATIONAL DATABASE! (TO BE REPLACED BY EUDAMED IN 2021)

STERILE PRODUCT? NOTIFIED BODY (NB) INVOLVED FOR PRODUCT TYPE APPROVAL AND MONITORING MASS PRODUCTION. MANUFACTURER CERTIFIED TO ISO 13485

CE xxxx

XXXX IS FOUR-DIGIT NB ID

PROTECT THE HEALTH STAFF

RESPIRATORY DEVICE

PERSONAL PROTECTIVE EQUIPMENT (PPE) REGULATION

EN 149:2001+A1:2009

CLASS FFP2 or FFP3*

PRODUCT TYPE APPROVAL VIA NOTIFIED BODY (NB)

MASS PRODUCTION MONITORED BY NOTIFIED BODY

CE xxxx

XXXX IS FOUR-DIGIT NB ID

* CLASS FFP1 IS NOT RELEVANT FOR APPLICATION IN HOSPITALS REGARDING CORONA THEREFORE THIS TYPE IS NOT IN THIS OVERVIEW

Marks and Certificates: Red Flags

- Is there a mismatch between the product and paperwork, or within the paperwork?
  - Products are not the same (includes description, model number, and branding) as what is identified on the certificate and what is indicated in shipping/import paperwork
- Is the certificate type applicable for that product type?
  - For example, an ISO 9001 Certificate does not support or validate the compliance of PPE such as masks, gloves, or gowns.
- If PPE or medical devices is marked with a CE + Four Digits, that should be reviewed further.
- *Caveat: There is an EC recommendation (EU) 2020/403 for PPE. Implementation is determined by member states, therefore current requirements must be confirmed with the national competent authority.*

Verification of EU – Type Examination Certificate PPE
(Respiratory Protection Masks are classified as Category III)

For the European Market two documents needs to be granted by a Notified Body of the European Community

1. Type Approval (Annex V/ Module B)
   The certificate needs to be clearly identified as a **EU – Type Examination Certificate**
   (documents as "Certificate of CE conformity" or Attestation of Conformity" only indicates that the issuing party evaluated the conformity of the product however does not have any legal effect)

2. Evaluation of internal quality assurance system of manufacturer
   a) (Annex VII /Module C2) product verification tests or
   b) (Annex VIII /Module D) quality assurance of production process

The certificate needs to be issued by a Notified Body of the EU. The number of Notified Body used for step 2 will be indicated on the CE xxxx

Notified Body Code

Each Notified Body of the European Community is identified by a specific code.
In areas where a Notified Body needs to be involved (e.g., PPE) the product needs to show a CE mark with the four (4) digit code of the related Notified Body.
The Notified Body as well as its scope can be easily identified via “NANDO” database.

https://ec.europa.eu/growth/tools-databases/nando/

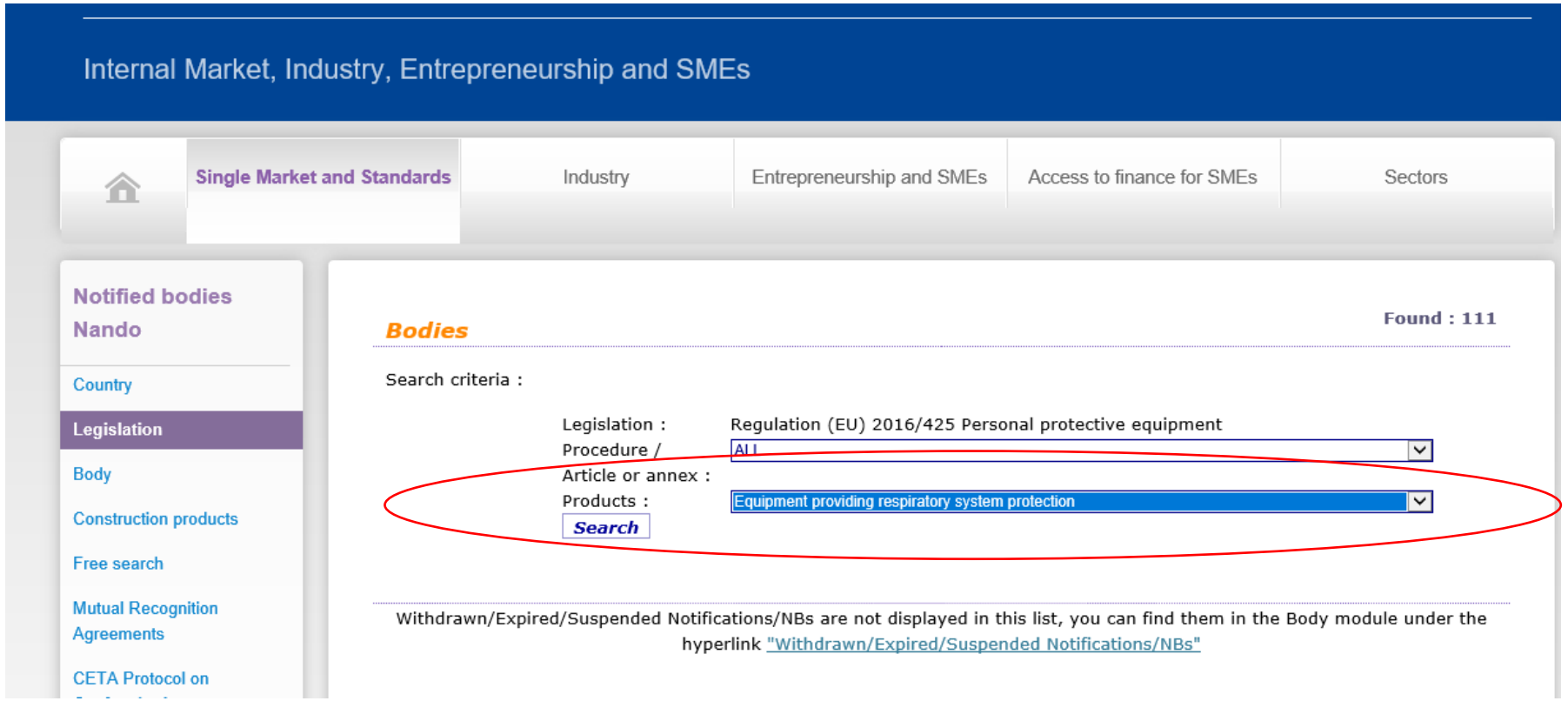
CE XXXX

Verification of EU – Type Examination Certificate PPE for Respiratory Protection Masks

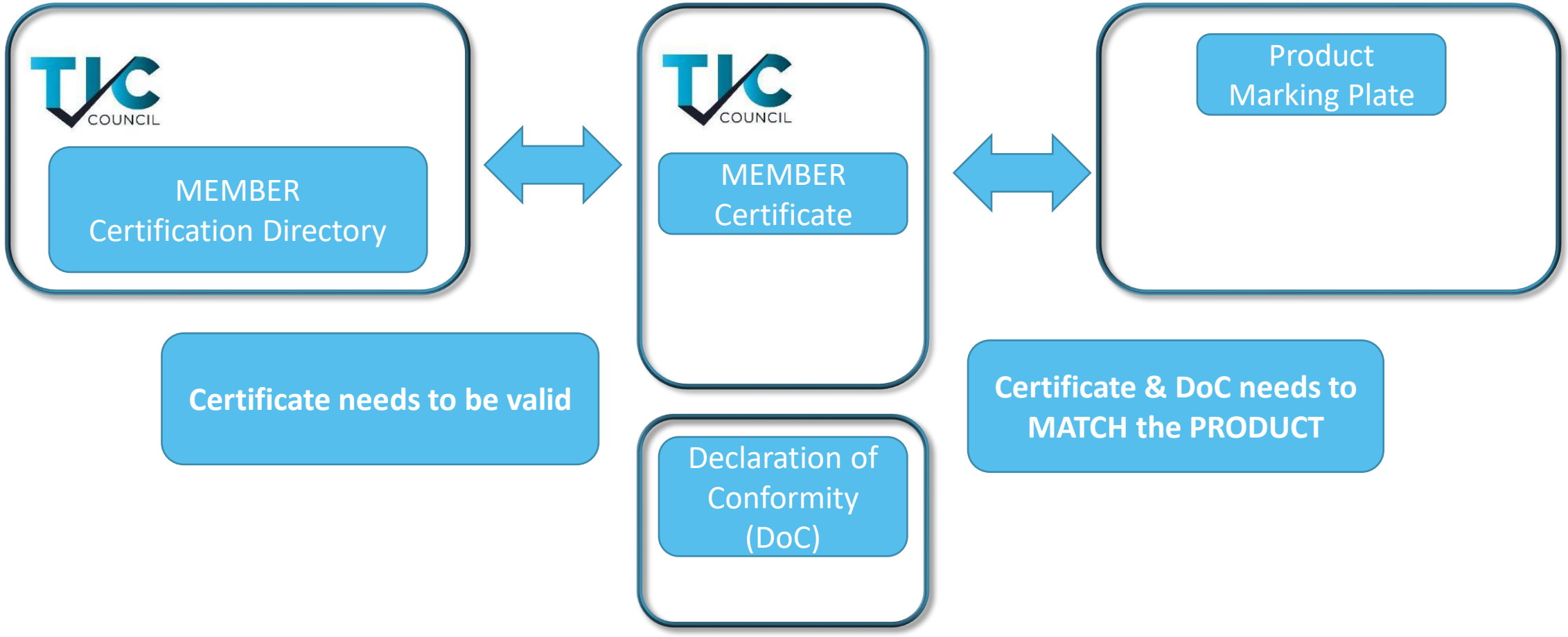
With a few clicks you will come to the Search for Notified Bodies under PPE (currently around 111 listings)

The following link is a short cut
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

In the drop down menu for „products“ please select: *Equipment providing respiratory system equipment*“ which will lead to actual 34 listed Notified Bodies



Helpful Hints: Reviewing Key Information: Product, Certificate and Certification Directory



If core information is NOT 100% identical, contact relevant Certification Body

Validating Marks and Certificates

TIC Council recommends that authorities and purchasers of PPE equipment and/or medical devices verify the validity of any claims of compliance and certificates of conformity. This includes:

(1) Requesting a certificate;
(2) Validating the certificate or product Certification Mark by contacting the identified Certification Body;
(3) If you cannot identify or contact the Certification Body contact the TIC Council Secretariat (secretariat@tic-council.org).

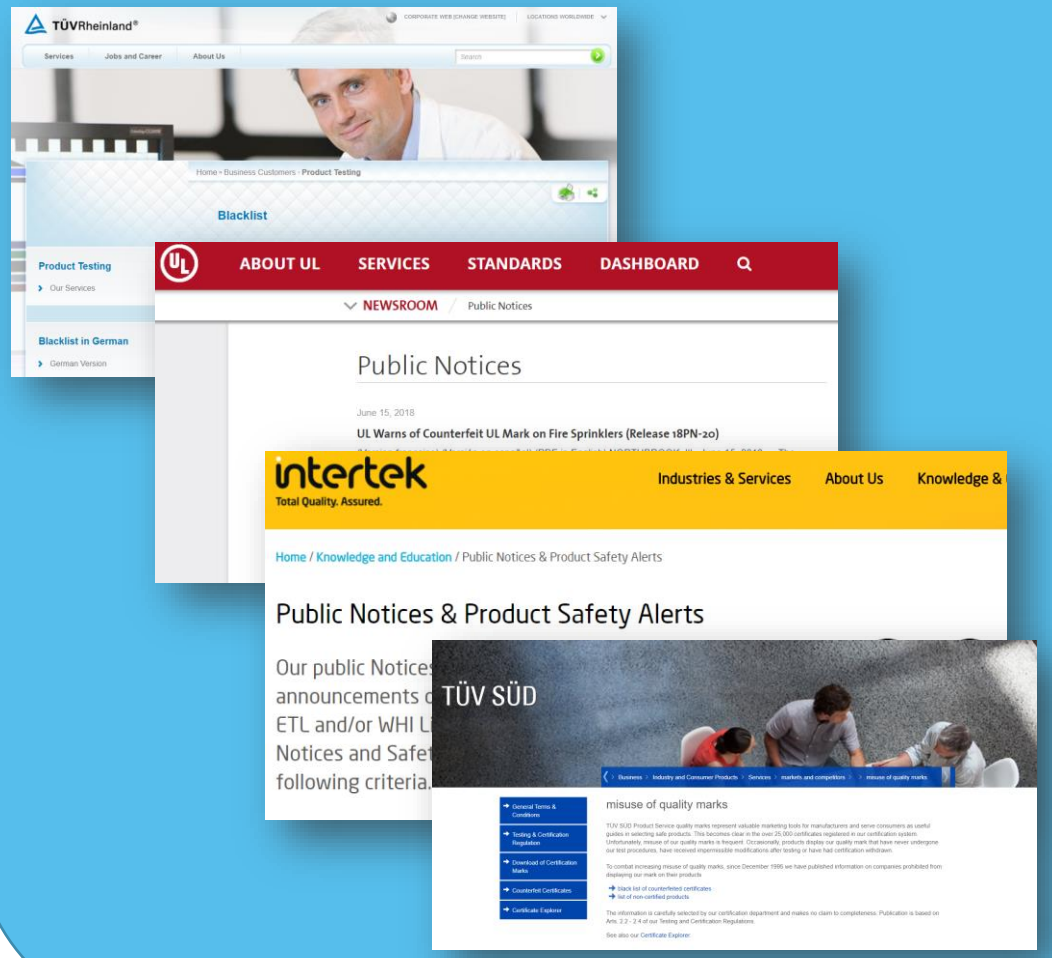
Certification Body Quick Reference

	TIC Council Member	*Verification Database*
CONTROLUNION	**Control Union** **www.controlunion.com**	certifications.controlunion.com/en
DEKRA	**DEKRA** **www.dekra.com**	dekra-product-safety.com/en/about-dekra/certified-products
eurofins	**Eurofins** **www.eurofins.com**	**https://www.eurofins.com/certifications-international-approvals/**
intertek Total Quality. Assured.	**Intertek** **www.intertek.com**	intertek.com/directories
SGS	**SGS** **www.sgs.com**	sgs.com/en/certified-clients-and-products
TÜVRheinland® Precisely Right.	**TÜV Rheinland LGA Products GmbH** **www.tuv.com**	certipedia.com
TÜV SÜD	**TÜV SÜD Product Service GmbH** **www.tuev-sued.de**	**https://www.tuvsud.com/ps-cert**
UL	**UL** **www.ul.com**	ul.com/database

Other Efforts to Fight Counterfeiting

Education

Public Awareness



Coming Soon…

White Paper: *Identification and Impact of Counterfeit Test Reports and Certificates in the Global Marketplace*

If you are interested in receiving a copy upon its release, please contact:

secretariat@tic-council.org

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Wikipedia page:
Testing, inspection and certification

TIC-Council.org