



Conformity assessment

Presented by: Karim Loukil & Kaïs Siala



Today's Objectives

- ➔ • Present basic information about conformance and conformance related topics
- Address:
 - What is Conformance?
 - What does it mean to conform?
 - How do you know a system conforms?
 - What do you need to do testing?
 - Who does the testing?



The Benefits of Meeting the Challenges...



For your citizens:

- ***Greater product availability***
- ***More choice***
- ***More confidence***
- ***Lower cost of goods and services***

For the Economy:

- ***More Trade***
- ***Faster Growth***
- ***More Capital Investment***

For All Manufacturers:

- ***Faster Time to Market***
- ***Lower Cost***
- ***More Effective Competition***
- ***More Investment Opportunity***

Definitions

- 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to radio equipment have been fulfilled;
- 'conformity assessment body' means a body that performs conformity assessment activities;
- 'CE marking' means a marking by which the manufacturer indicates that the radio equipment is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.
- Market surveillance: "Measures by public authorities to ensure that a product made available on the market comply with existing requirements""

Accreditation

- The accreditation process determines, in the public interest, the technical competence and integrity of organisations offering testing, examination, inspection, calibration, verification and certification services.
- It operates across all market sectors, providing an impartial assessment against internationally recognised standards, which
 - provides a transparent approach to conformity assessment in all sectors
 - supports Regulations across a growing number of policy areas.



Regulation (EC) No 765/2008



- In 2008, the European Council of the European Union and the European Parliament agreed Regulation 765/2008 that provides a legal framework for the provision of accreditation services across Europe



European
co-operation for
Accreditation

- Peer evaluation
(ISO/IEC 17011)
- Regulation (EC)
No 765/2008

**National
Accreditation
Bodies (NABs)**

NABs assess and confirm the technical competence and integrity of organisations offering testing, examination, inspection, calibration, verification and certification services.

Laboratories

Laboratories (calibration, testing and medical) perform tests and/or calibrations

ISO/IEC 17025
ISO 15189

Inspection Bodies

Bodies that perform inspections of products, installations, etc

ISO/IEC 17020

Certification Bodies

Bodies that assess conformity, and certify products, management systems, persons, processes or services

ISO/IEC 17021
ISO Guide 65 (EN 45011)
ISO/IEC 17024

Verification Bodies

Bodies that carry out validation or verification of greenhouse gas assertions

ISO 14065

NABs assess compliance with the requirements in international standards, as well as criteria included in Regulations.

Terminology - Conformance

- **CONFORMANCE** – the fulfillment of a product, process or service of specified requirements. (*ISO Guide 2*)
 - The requirements are specified in a standard or specification as part of a conformance clause or in the body of the specification
- **CONFORMANCE CLAUSE** - a section of a specification that states all the requirements or criteria that must be satisfied to claim conformance



Terminology - Conformance Testing



- **CONFORMANCE TESTING** – a way to determine directly or indirectly that relevant requirements are fulfilled.
 - Serves as a communication between buyer and sellers
 - Buyers increased confidence
 - Sellers substantiate claims
 - Necessary, but not sufficient, for interoperability

Note: referred to as conformity assessment in ISO Guide 2



Terminology - Testing Process



- **CERTIFICATION** - acknowledgement that a validation was completed and the criteria established for issuing certificates (brands) was met.



Certification

qualified bodies to do the testing and certification
control board

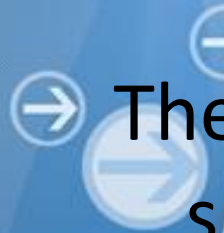
Conformance Testing

Test suite

Standard

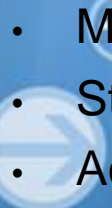
Conformance clause

Accreditation

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- The assessment – documentary and on site - includes
 - quality systems
 - administrative procedures
 - working methods
 - technical competence

Annual surveillance, full re-assessment every 4th year

New Approach – necessary infrastructure

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- Metrology
 - Standardization
 - Accreditation
 - Authority to designate notified bodies
 - Notified bodies
 - Conformity assessment
 - Sector authorities
 - Market surveillance

CONFORMITY ASSESSMENT

MODULE A: INTERNAL PRODUCTION CONTROL

- Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of Annex A of RED,
- the manufacturer ensures and declares on **his sole responsibility** that the radio equipment concerned satisfies the essential requirements set out in Article 3.
- [European scheme for self declaration](#)

CONFORMITY ASSESSMENT

Module B EU-type examination

- EU-type examination is the part of a conformity assessment procedure in which a notified body examines **the technical design** of the radio equipment and verifies and attests that the technical design of the radio equipment meets the essential requirements set out in Article 3.
- EU-type examination shall be carried out by assessment of the adequacy of the technical design of the radio equipment through examination of the technical documentation and supporting evidence referred to in point 3, **without examination of a specimen** (design type).



CONFORMITY ASSESSMENT



Module C Conformity to type based on internal production control

- The manufacturer shall take all measures necessary so that the **manufacturing process and its monitoring** ensure conformity of the manufactured radio equipment with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to it.



CONFORMITY ASSESSMENT MODULE H CONFORMITY BASED ON FULL QUALITY ASSURANCE

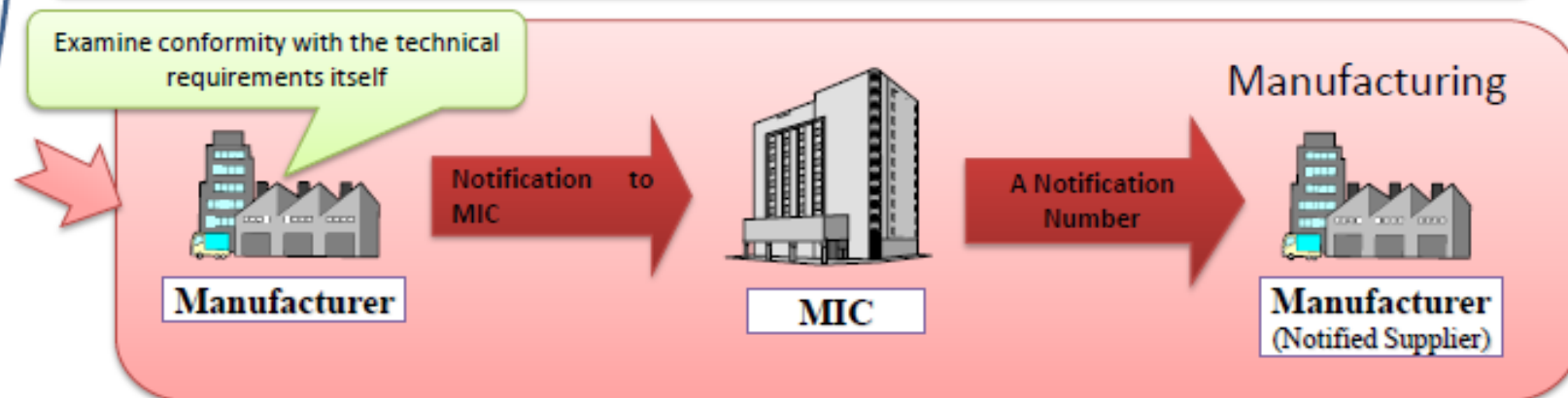
- The manufacturer shall operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

Certification System

- (1) Technical Regulations Conformity Certification (Tested and certified one by one)
- (2) Construction Type Certification (Conformity assessment of construction type)

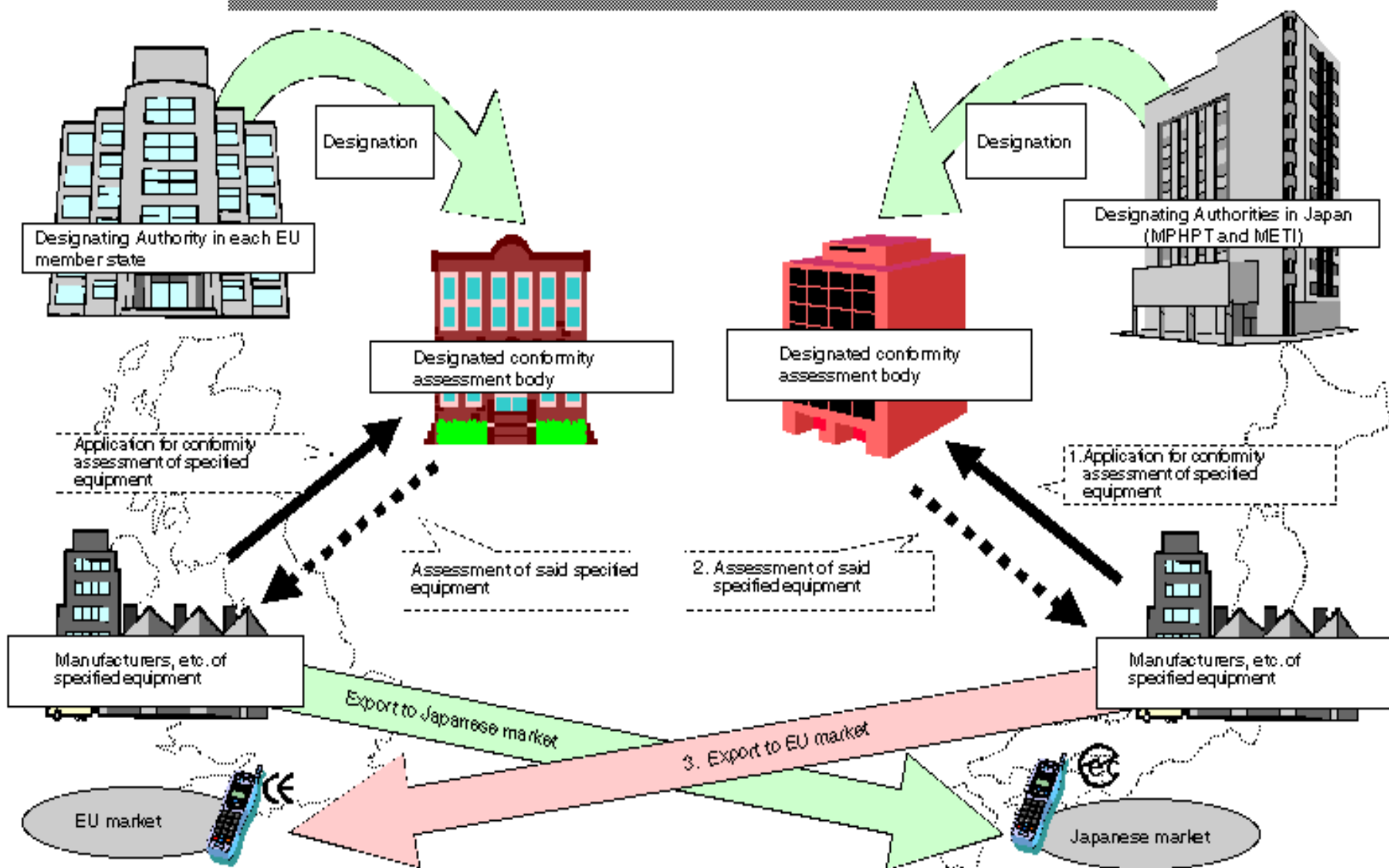


- (3) Self-Confirmation of Technical Regulations Conformity (Verification and confirmation itself)

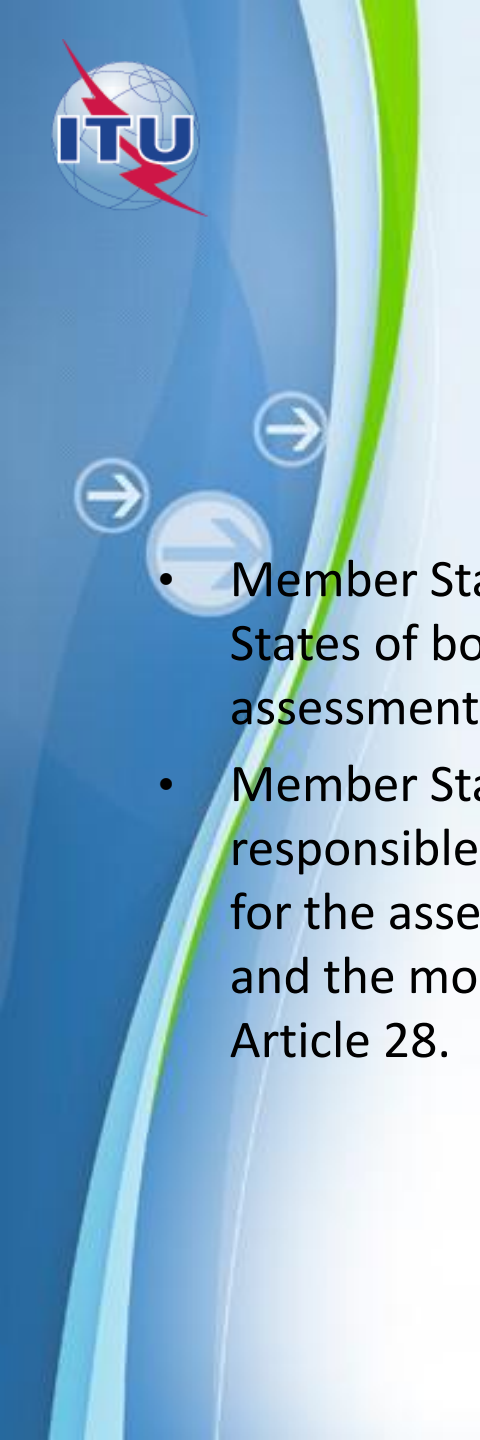




Outline of Japan-EU Mutual Recognition Agreement



Notification

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- Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under RED Directive.
 - Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 28.

Conformity assessment

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REGULATORY FUNCTIONS

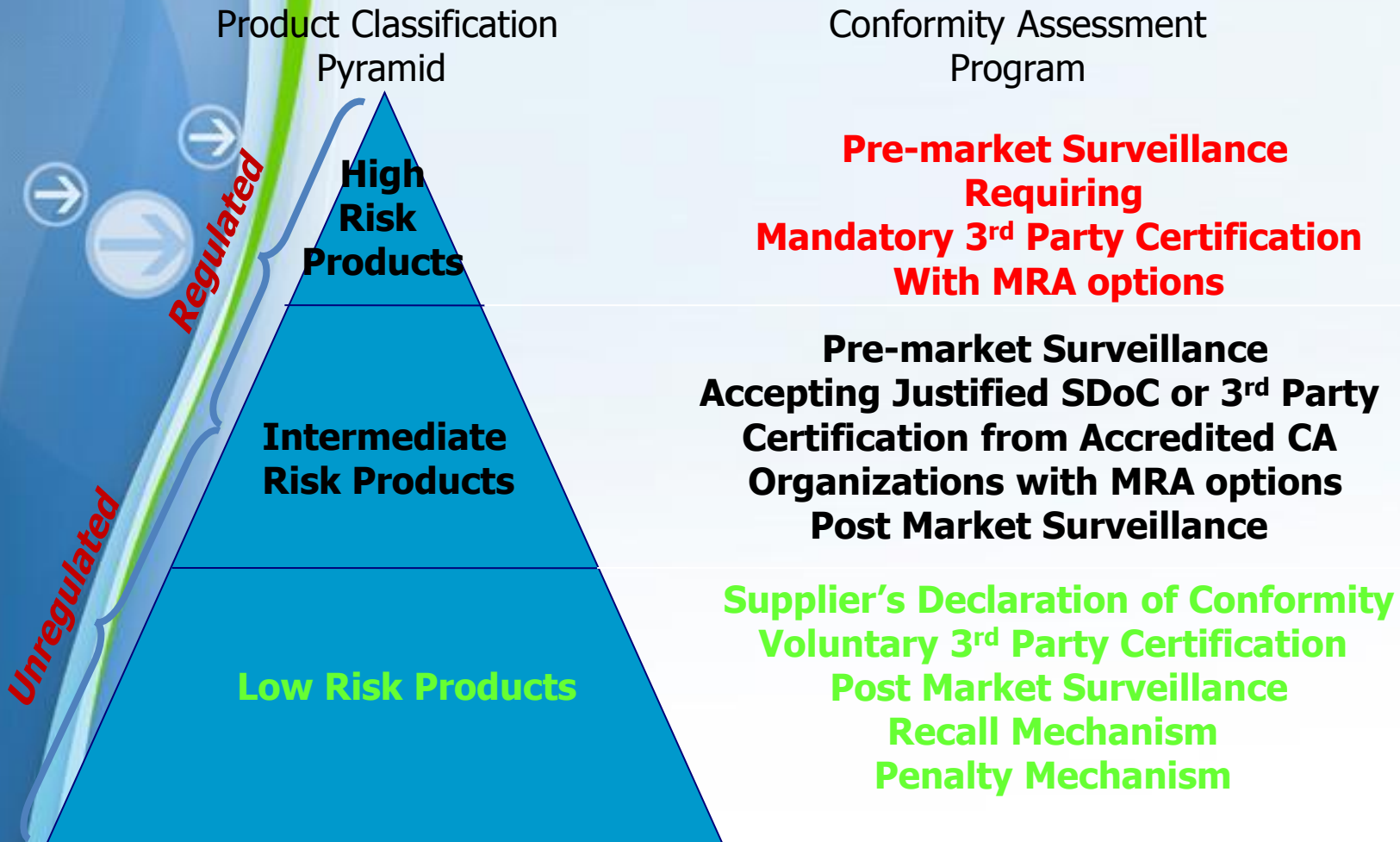
- Relevant ministries

EXECUTIVE FUNCTIONS

- Standardization Institute
- Accreditation Institute
- Bureau of Metrology
- Test Laboratories
- Calibration Laboratories
- Certification and Inspection Bodies

Industry Preferred

Conformity Assessment Model





	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	The Voluntary Control Council for Interference by Information Technology Equipment (VCCI)	VCCI V-3 report required	Product dependent some mandatory certification some via Declaration of Conformity (DoC)
Safety (Electrical) Requirement	Product Safety Electrical Appliance & Material (PSE)	IEC report with Japanese deviations (under CB Scheme)	DoC based on report and Construction File (CF)
Radio Requirement	Ministry of Internal Affairs and Communications (MiC)	Report required proving conformity to Japanese Radio Law and ordinances	MiC Conformity Assessment Body (CAB) review, leading to certification
Telecoms Requirement	MiC	Report required to prove conformity to Japanese Telecoms	MiC CAB review leading to certification

SOUTH KOREA

	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Radio Research Agency (RRA)	Required	For non-radio or non-telecoms products, the Korean Certification (KC) Mark certification can be obtained using ILAC accredited EU EMC Reports
Safety (Electrical) Requirement	Ministry of Commerce, Industry and Energy (MOCIE)	A CB Scheme report is accepted but only part covers eK requirement so samples will need to be provided	Most AC powered and some DC powered products require eK Mark Certification
Radio Requirement	RRA	Mandatory In Country Testing	KC Certification
Telecoms Requirement	RRA	Mandatory In Country Testing	KC Certification

	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Agência Nacional de Telecomunicações (ANATEL)	In Country Testing	ANATEL Certification
Safety (Electrical) Requirement	The National Institute of Metrology, Standardization and Industrial Quality (INMETRO)	Product Dependent, CB Reports can be used	INMETRO Certification
Radio Requirement	ANATEL	In Country Testing	ANATEL Certification
Telecoms Requirement	ANATEL	In Country Testing	ANATEL Certification

	Regulator	Mandatory Testing	Accepted Route
Safety (Electrical) Requirement	MB Saudi Standards, Metrology and Quality Organisation (SASO)	CB Scheme	
Radio Requirement	Communications and Information Technology Commission (CITC)	EU Test Reports	CITC Certification
Telecoms Requirement	CITC	EU Test Reports	CITC Certification



	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Australian Communications and Media Authority (ACMA)	AS/NZS (or equivalent) Report	Declaration of Conformity (DoC) for Regulatory Compliance Mark (RCM). Supported by Technical Construction File
Safety (Electrical) Requirement	Electrical Regulatory Authorities Council (ERAC)	AS/NZS (or equivalent) Report	For most products DoC, but please check with us
Radio Requirement	ACMA	AS/NZS (or equivalent) Report	Doc for RCM. Supported by Technical Construction File
Telecoms Requirement	ACMA	AS/NZS (or equivalent) Report	Doc for RCM. Supported by Technical Construction File

Please be aware you will need a representative in Australia



New Zealand

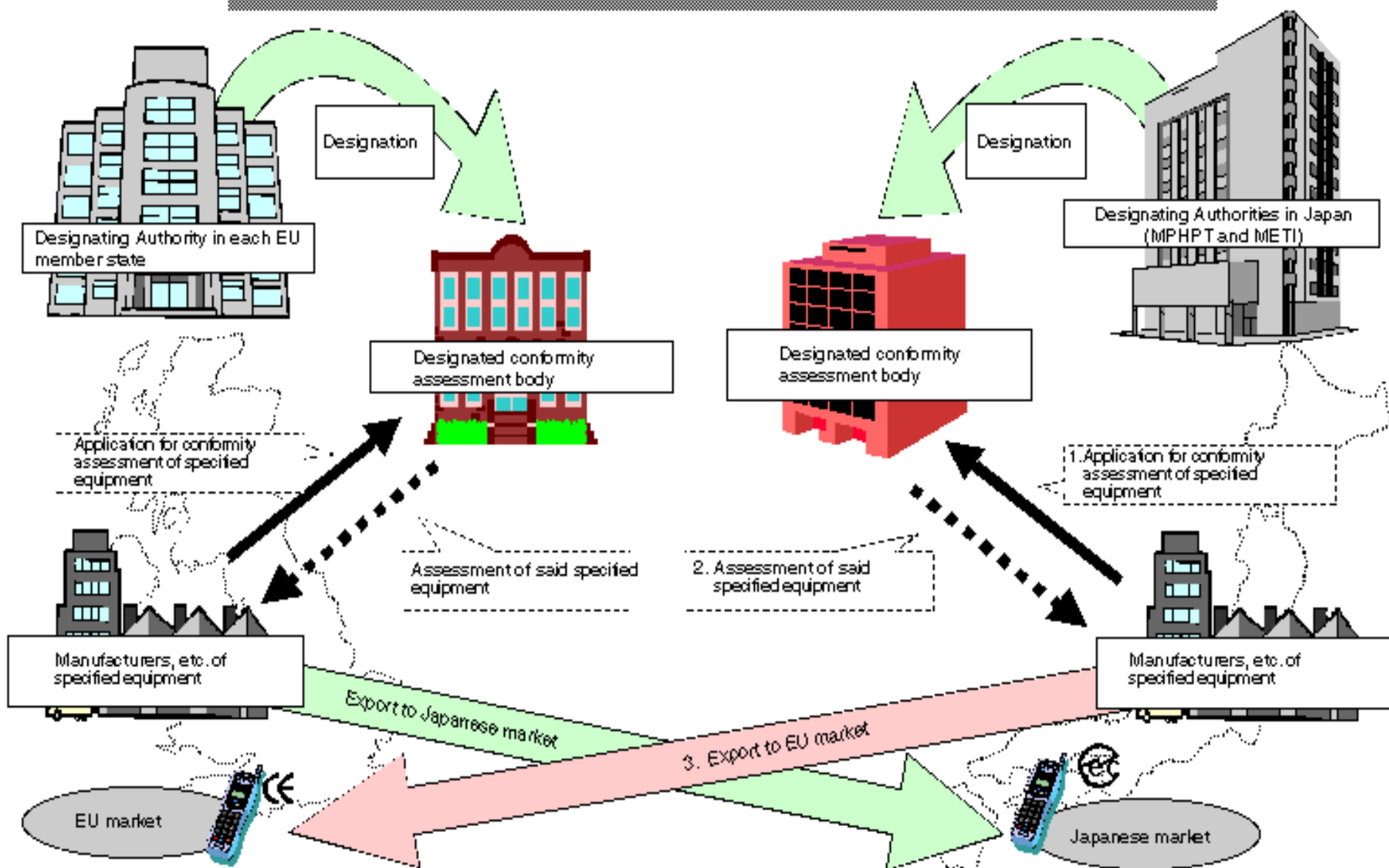


	Regulator	Mandatory Testing	Accepted Route
EMC Requirement	Australian Communications and Media Authority (ACMA)	AS/NZS (or equivalent) Report	Declaration of Conformity (DoC) for Regulatory Compliance Mark (RCM). Supported by Technical Construction File
Safety (Electrical) Requirement	Electrical Regulatory Authorities Council (ERAC)	AS/NZS (or equivalent) Report	For most products DOC (please check with our approvals experts)
Radio Requirement	ACMA	AS/NZS (or equivalent) Report	Doc for RCM. Supported by Technical Construction File
Telecoms Requirement	Telecoms NZ	For the majority of products PTC (or equivalent)	Telepermit Certification

Please be aware you will need a representative in New Zealand.



Outline of Japan-EU Mutual Recognition Agreement





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Presented by: Karim Loukil & Kaïs Siala

Karim.wakil@cert.mincom.tn

Kais.siala@cert.mincom.tn

