

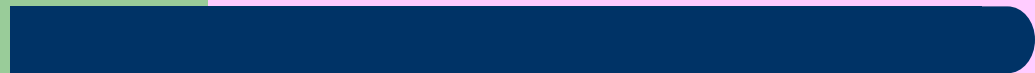
Welcome to presentation
by



Netpeckers
Excellence for eternity.

NETPECKERS CONSULTING (P) LTD.

An ISO 9001:2000 compliant organization



On
Advantages, importance & procedure of implementing
CE Marking



CE stands for



Conformance Europa



Is a product standard

- For manufacturers interested in exporting their products to any country in European Union or European Economic Area (EEA)

How do you start

- What is the type of product that you have
- As there are Directives defined for category of products, Identify the right Directive.

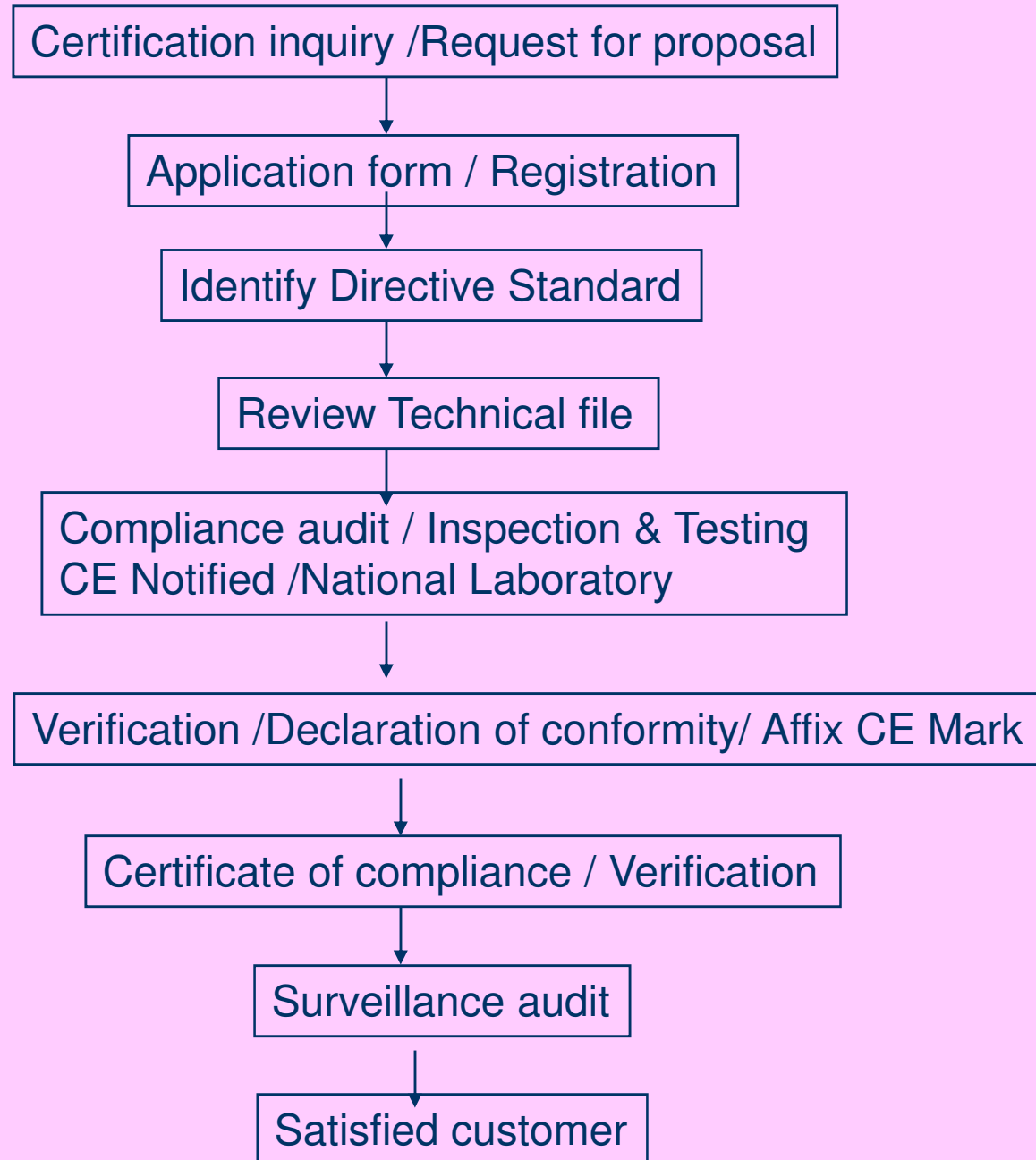


Medical Device Directive

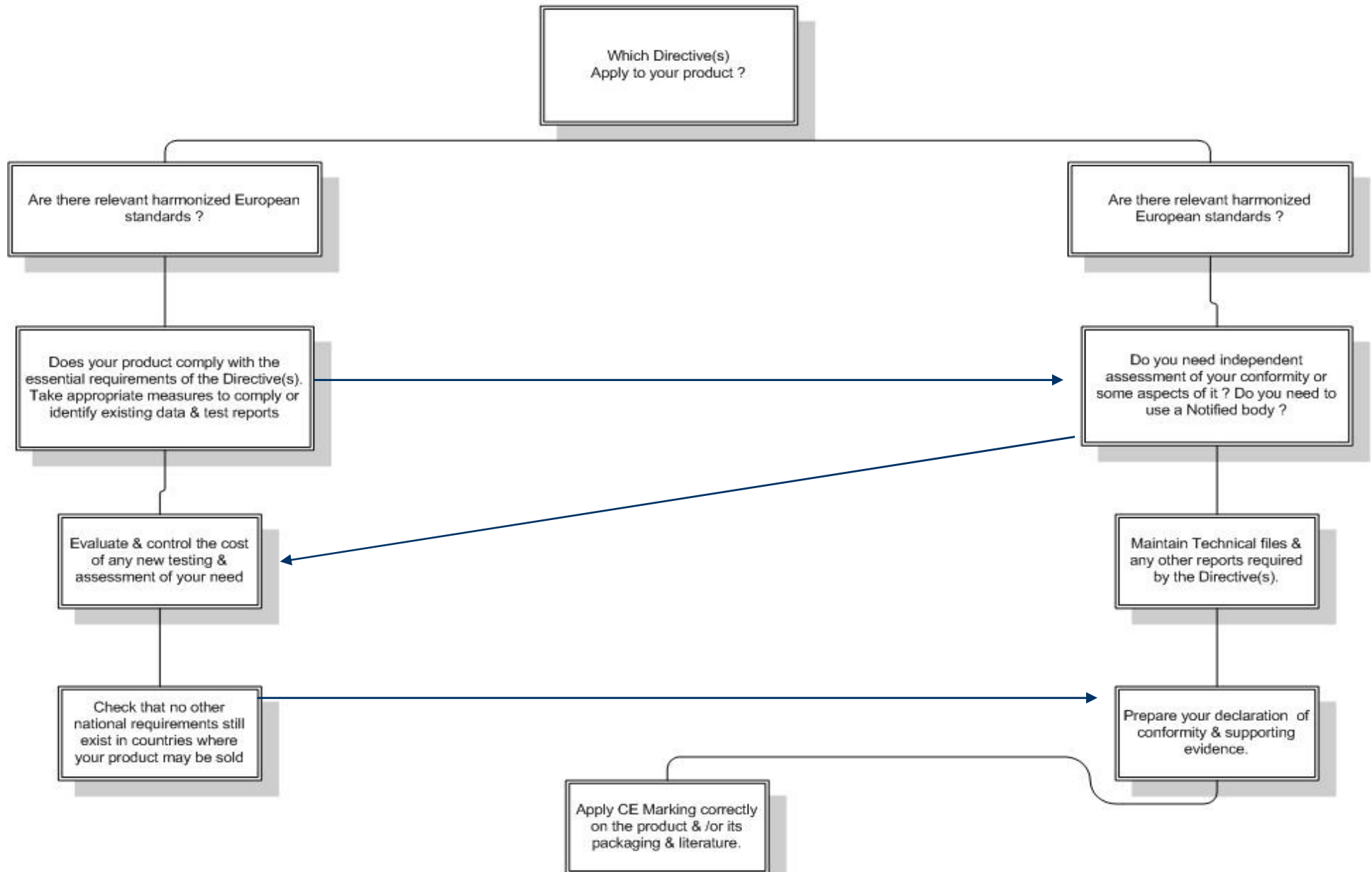
- Active implantable devices
- Medical devices
- Disposables
- Accessories
- Lab instruments & gadgets



CE Marking process @ Netpeckers Consulting (P) Ltd.



CE Marking process



Available Directives

- Medical Devices (MDD)
- New hot water boiler
- Gas Appliances
- Explosives for civil uses
- Recreational craft
- Non automatic weighing Instruments
- Active implantable medical devices
- Equipment for explosive atmosphere
- Telecommunication terminal equipments
- Satellite earth station for telecom
- Lifts
- House hold appliances (Energy efficient)
- Pressure equipment devices
- Low voltage equipment (LVD)
- Simple pressure vessel
- Safety for toys
- Construction products (CPD)
- Electromagnetic compatibility (EMC)
- Machinery safety
- Personnel Protection Equipment (PPE)
- Marine equipments
- Other industry



Conformity Assessment Procedure

Self Declaration

Manufacture
Performa
Assessment

Manufacturer's
Technical file

Manufacturer
Issues declaration of
conformity & affixes
CE Marking

Voluntary Certification

CE Notified &
Competent body
Assessment

Manufacturer's
technical file with EC
body report

EC body issues
certificate & Approval
mark

Declaration of
conformity & Affixes
CE Marking by
Manufacturer

Mandatory Certification

Examination by CE
Notified & Competent
body

Assessment by EC
body

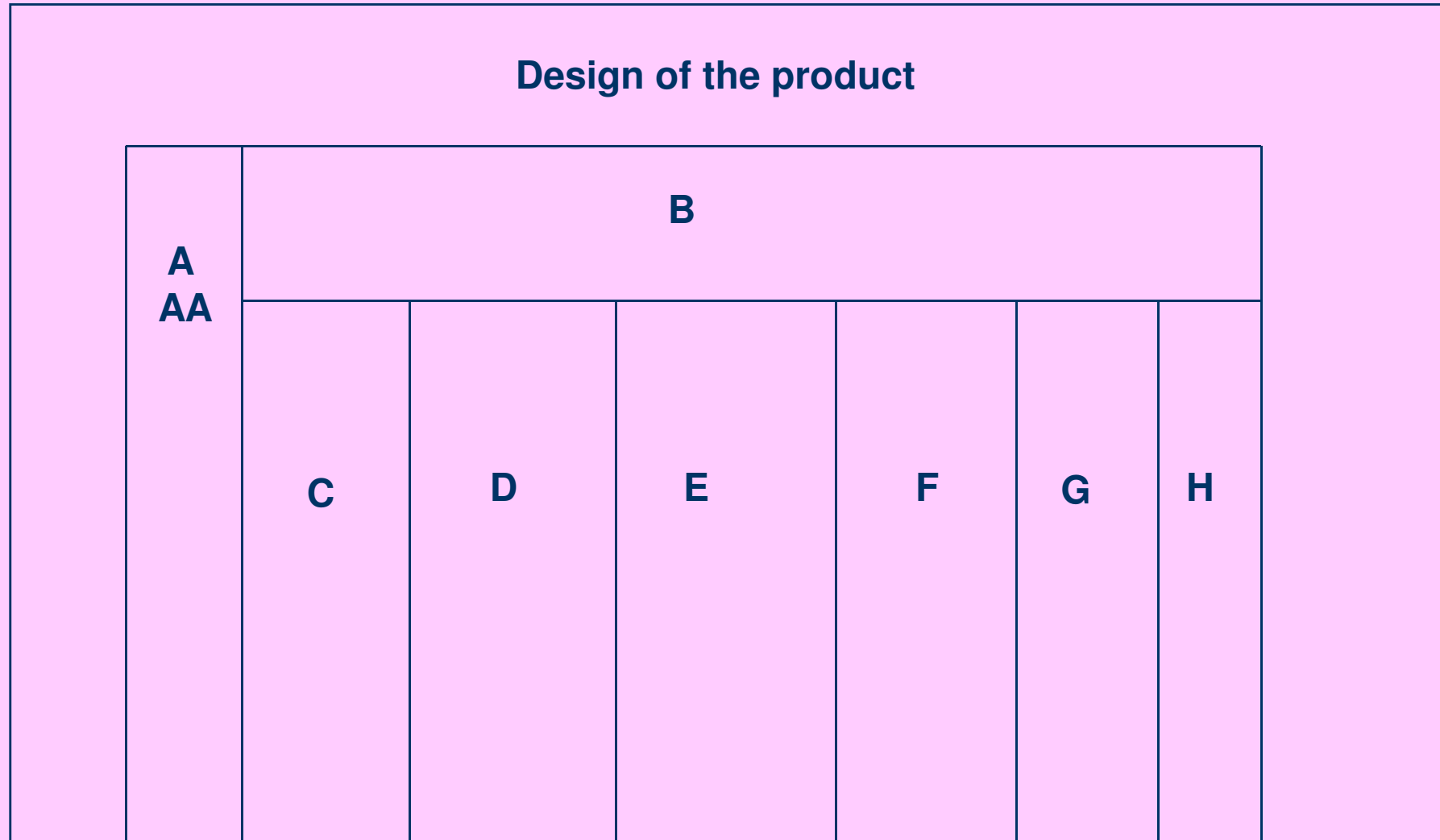
Technical file with EC
body report

EC Body issues
certificate & approval
mark

Declaration of
conformity & Affixes
CE Mark by
manufacture.



H Module system for selection

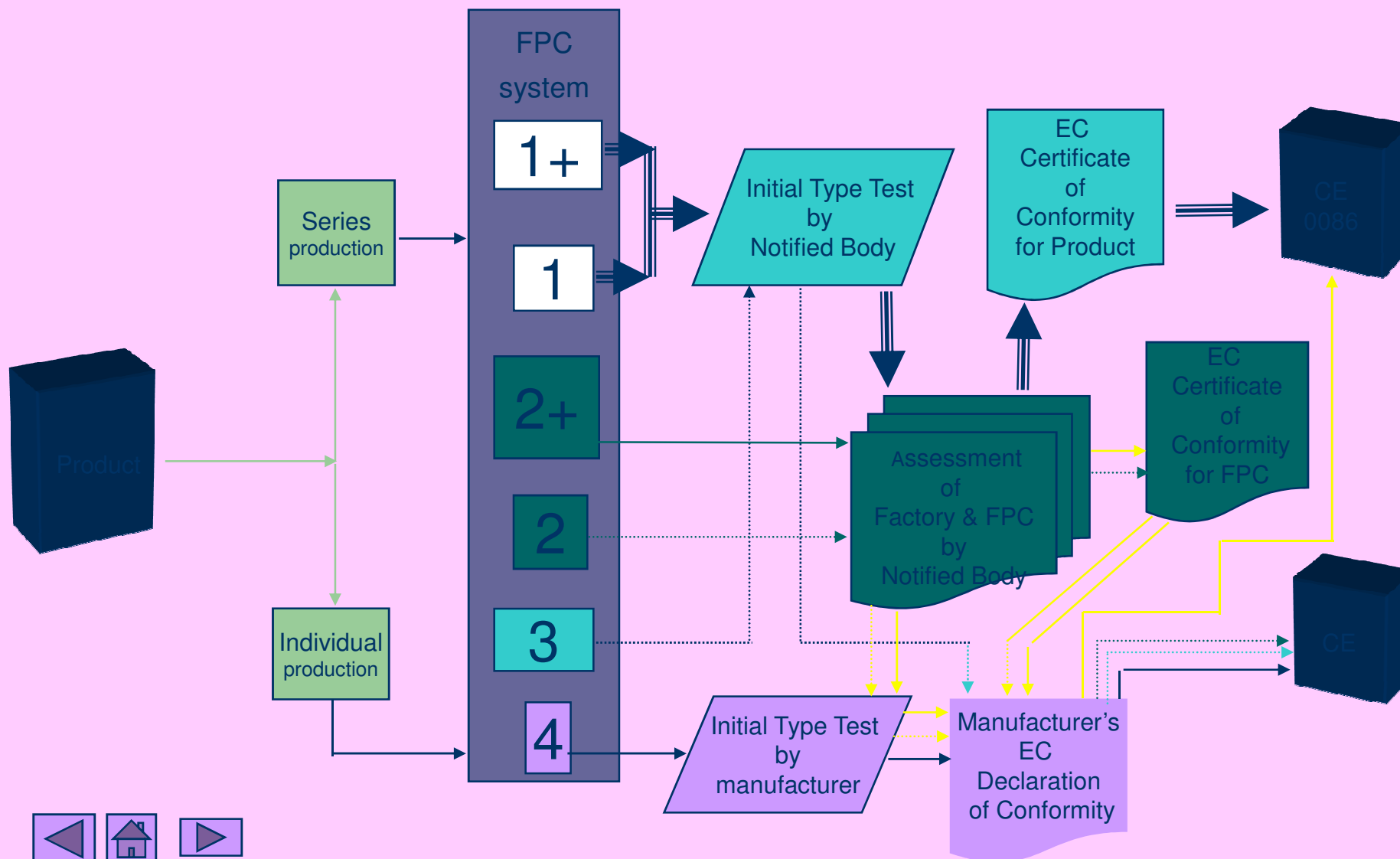


Legends

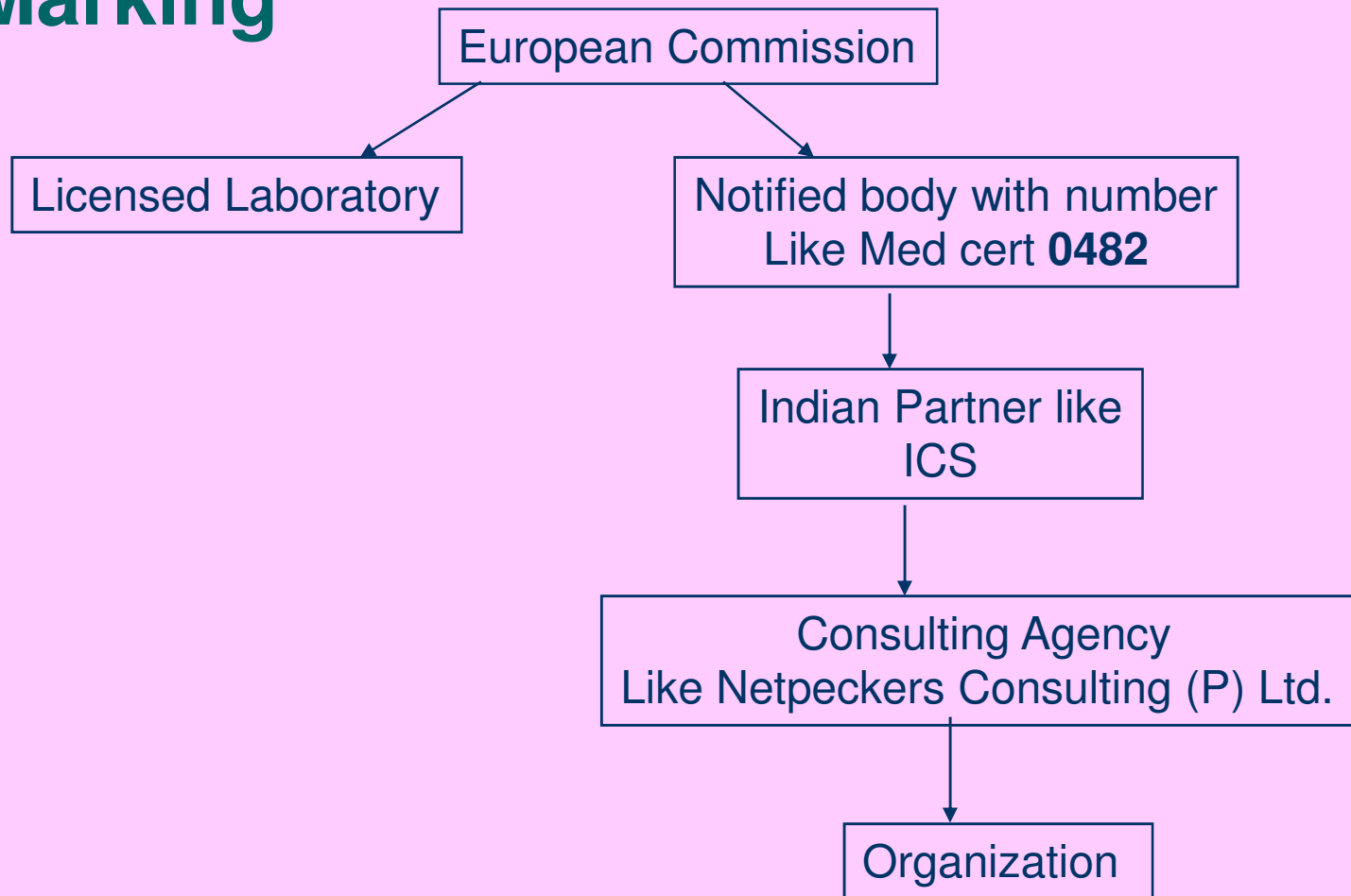
- A – Internal control of production
- B – EC Type examination
- C – Conformity of type
- D – Production quality assurance
- E – Production quality management
- F – Product verification
- G – Unit verification
- H – Full quality system



Pathway to affixing the CE



Structure of bodies governing CE Marking



Technical file consists of

- Quality management system docs. Like ISO 9001 : 2000
- Review other standards applicable like
- ISO 13485 – EN 46001-2-3
- BIS 13488

Assessment procedure for MDD

- Select from Non-active device(rule 1,2,3,4)
- Time of continuous use
- Invasiveness (rule 5,6,7,8)
- Active devices (9,10,11,12)
- Special rules (13-18)

How to decide continuous use on patient

- Transient – less than 30 minutes
- Short term – less than 30 days
- Long term – more than 30 days



Type of Invasiveness

- Non invasive
- Invasive through body orifice
- Surgical invasive
- Implantable device

Class IA – Self certification

- Annexure VII of MDD
- Others need to be assessed on product & company basis.



How do you start

- Details needed are
 - Filling the Quotation Request form
 - Providing complete details about the production & marketing of product
 - Target countries in Europe to sell
 - We assess & provide complete road map with techno-commercial proposal for the same based on information provided by you.



**Thank you for joining in the presentation
Please fill in the feedback form
Which would help us to be more precise
In our efforts.**

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An ISO 9001:2000 complaint organization

