ASIAN HARMONIZATION
WORKING PARTY

Working Towards Harmonization in Medical Device Regulation

3rd AHWP Technical Committee Meeting

29 – 30 April 2004
Taipei, Chinese Taipei

Risk-based Classification of Medical Devices in the European Union (GHTF): Point of View from a Notified Body

Lars-Oliver Huber

Operations-Director Pacific\Korea
Medical – Health – Sports
TÜV Product Service Japan Ltd.

Contents

- Why classification?
- Conformity Assessment Procedures
- How the system works
- The classification rules
- Examples
- Responsibilities

List of Abbreviations

- **EU** European Union
- **NB** Notified Body
- **MD** Medical Devices
- **CAP/B** Conformity Assessment Procedure / Bodies
- **AIMD** Active Implantable Medical Devices Directive
- **MDD** Medical Devices Directive
- **IVD** In-Vitro Diagnostic Medical Devices Directive
- **CEC** Commission of the European Communities

WHY Classification?

- **WHY, even though all medical devices must fulfil the unique set of "Essential Requirements"?**
  - **Medical devices comprise a very broad spectrum of devices;**
  - **Conformity Assessment Bodies need to be able to apply different "levels of control"**
  - **Different Conformity Assessment Procedures (CAP's) should be adopted depending on the risks imposed by those devices**

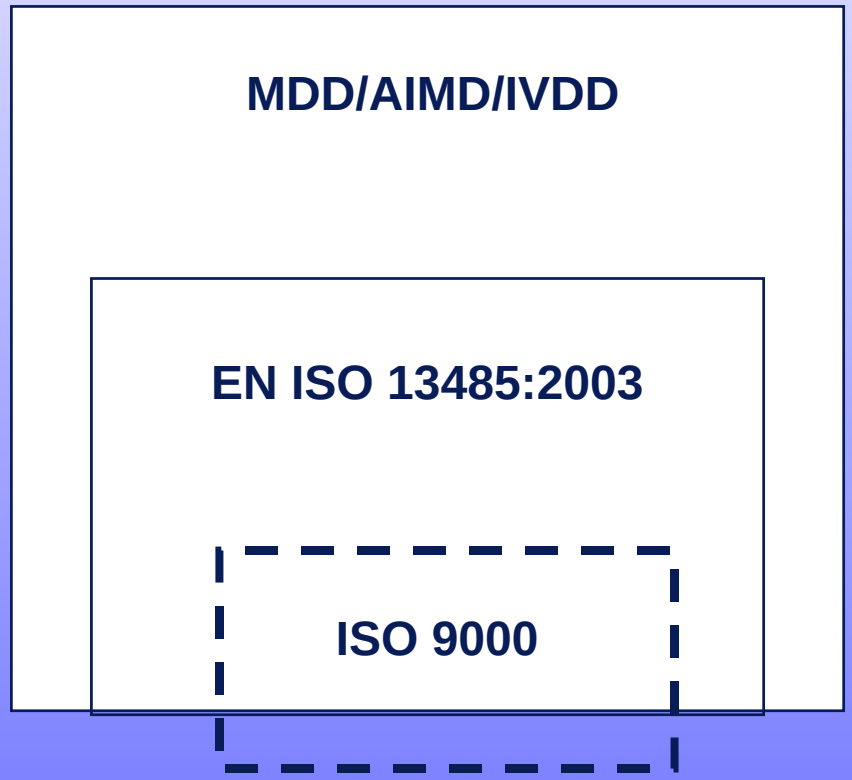
Risk Determines Requirements

CAP's / Product

- **Essential Requirements (annex I, MDD)**
  - All products require Technical Documentation
- **Product testing and Certification**
  - **according to harmonized European standards**
  - **in some cases product testing or Design Evaluation by the Notified Body mandatory (class III)**
  - **in some cases testing can be done by manufacturer himself or other accredited test laboratory**
    - test reports and test capability will be checked during audits.

CAP's / Quality System

- **Quality System Auditing and Certification**



Additional Requirements of the Directives themselves

EN - ISO13485 (medical devices - Quality Management Systems - requirements for regulatory purposes)
(Soon to be harmonized)

(ISO 9001:2000)

CAP's / Quality System

EN-ISO 13485:2003

- Medical devices - Quality Management Systems - requirements for regulatory purposes)
- Replaces EN-ISO 13485/8:2000 which reflected ISO 9000 requirements for Medical devices, still not harmonized, wherefore compliance to old version should still be demonstrated
- Is based on ISO 9001:2000 but excludes some requirements
- => Now stand alone
- Created by TC 210 under the MoU with the GHTF
  - http://www.ghtf.org/mou/ghtf-MoU.PDF
- Similar to new US Quality System Regulation

CAP's

- Annex II - Full Quality System (based on ISO 13485)
- Annex III - Type Examination
- Annex IV - Type Verification
- Annex V - Production Quality System (based on ISO 13485 excluding Design)
- Annex VI Product Quality System (based on the valid EN46003, successor not clear yet)
- Annex VII - Self Declaration

Class I

Annex 7
Declaration of Conformity
Technical File

Sterile (S) or measuring function (M)

Non-sterile, no measuring function

M | M | S, M | M

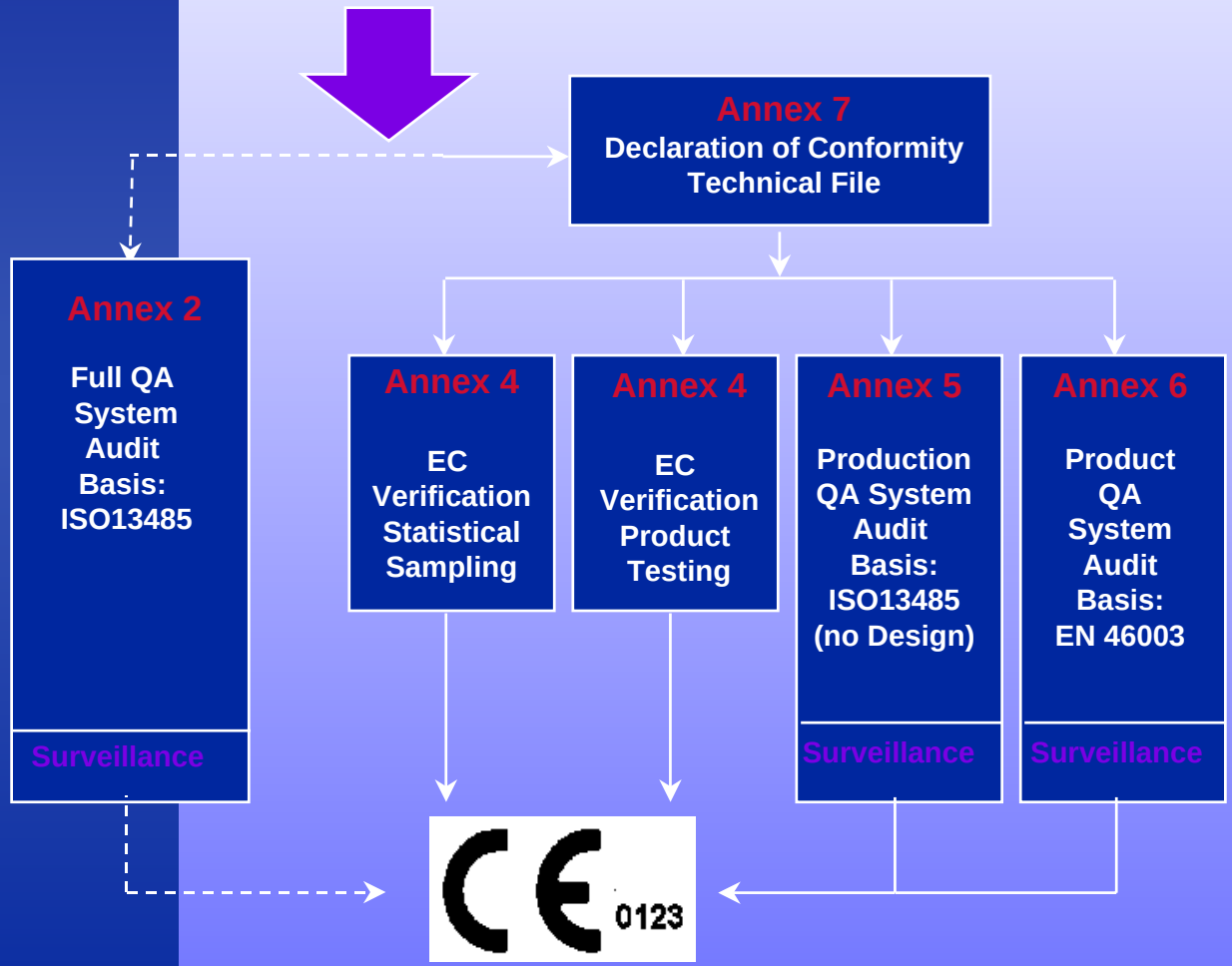
Annex 4
EC Verification Statistical Sampling

Annex 4
EC Verification Product Testing

Annex 5
Production QA System Audit Basis: ISO 13485 (no design)
Surveillance

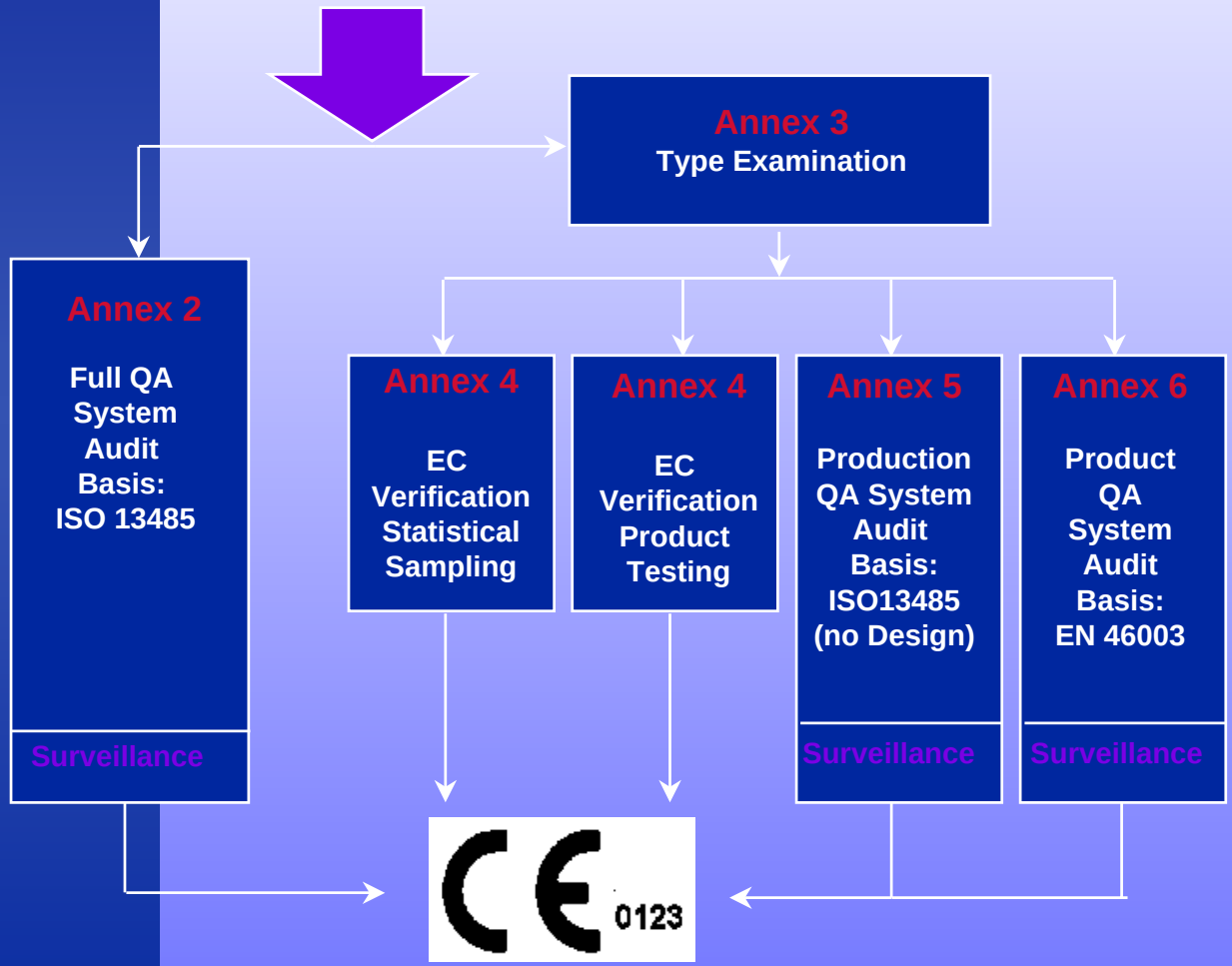
Annex 6
Product QA System Audit Basis: EN 46003
Surveillance

Class IIa



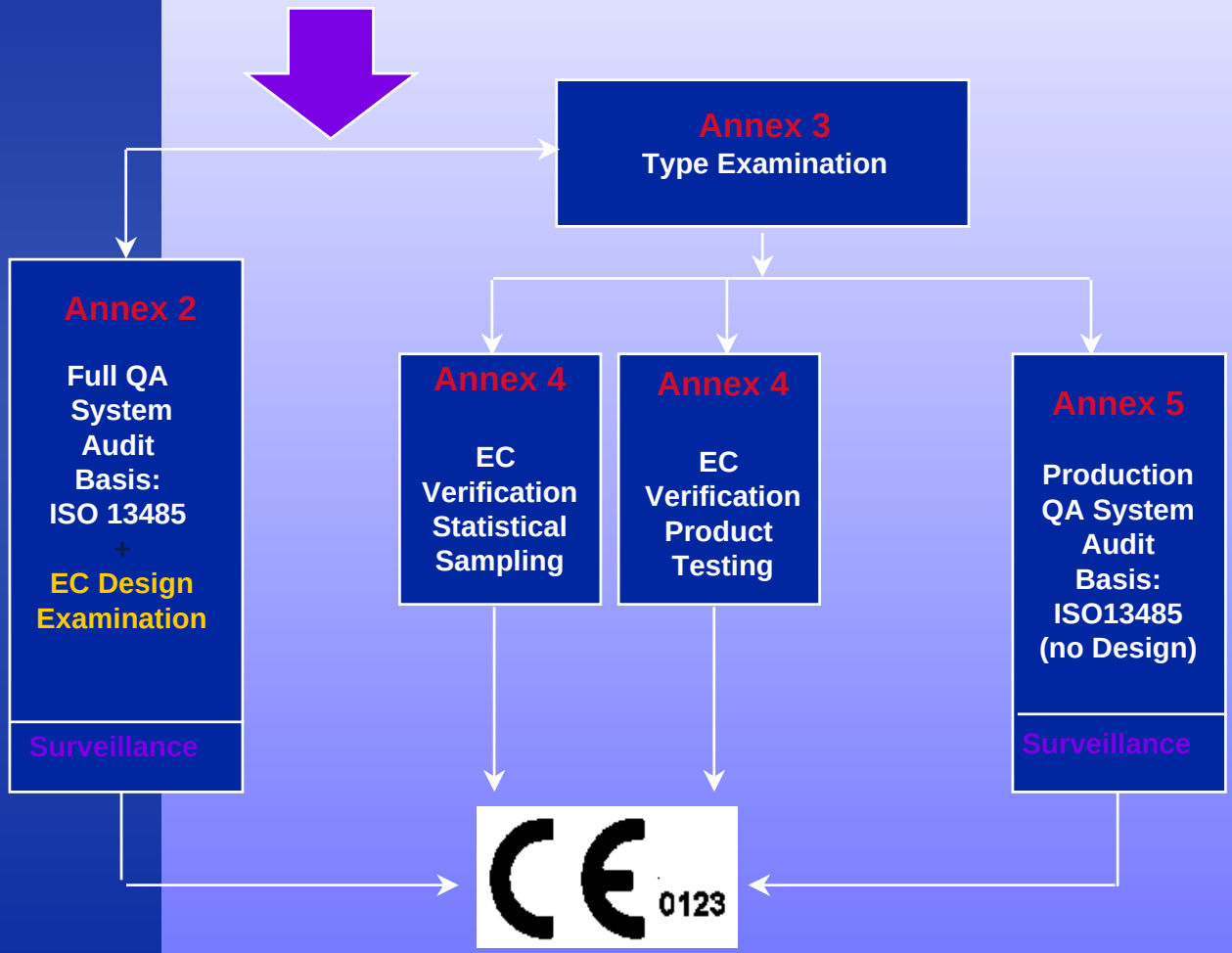
Annex 4 and 6 not possible if special processes are involved (Sterilization)

Class IIb



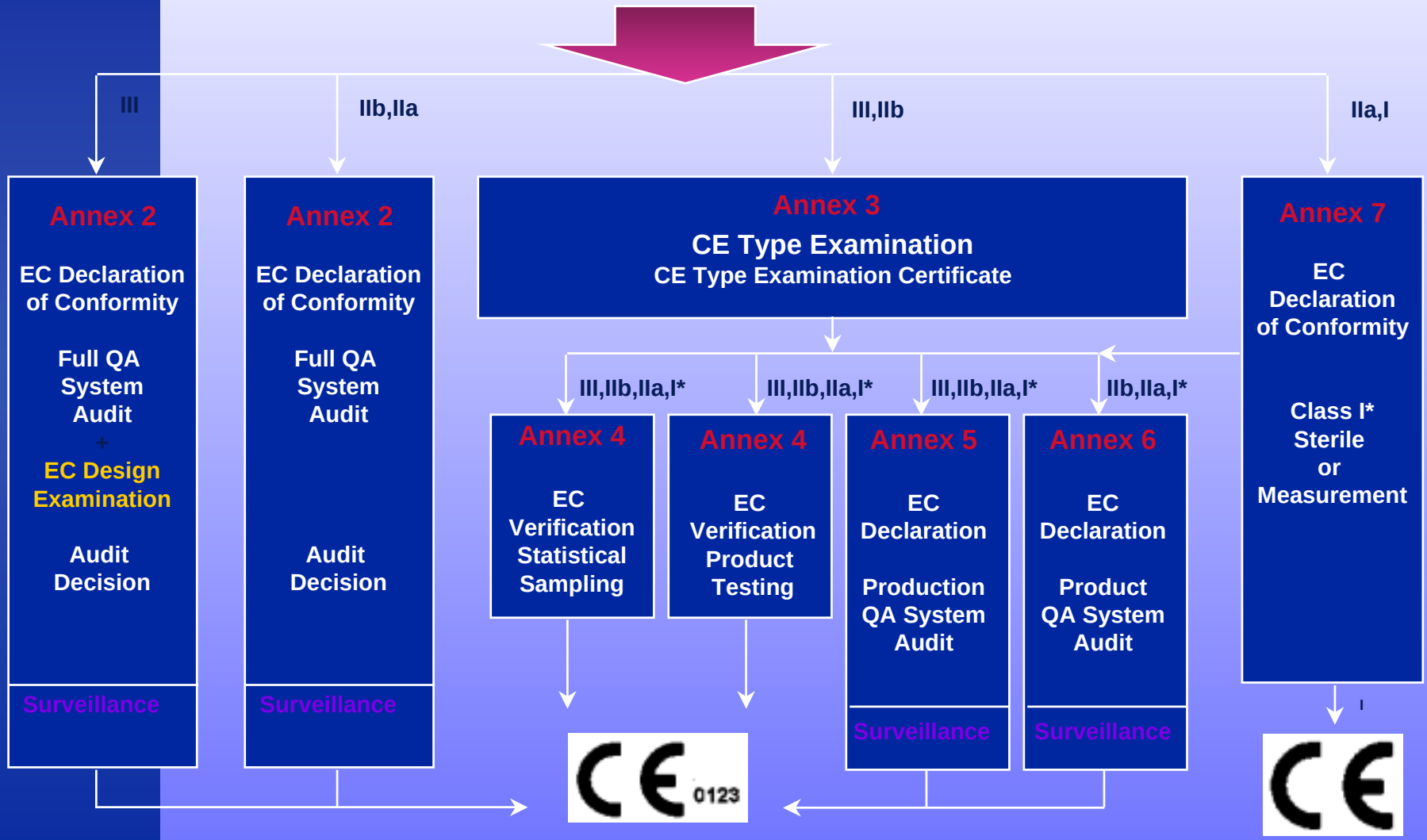
Annex 4 and 6 not possible if special processes are involved (Sterilization)

Class III



Annex 4 and 6 not possible if special processes are involved (Sterilization)

Conformity Assessment Modules



How to classify?

- **OPTIONS: by lists, or by rules**
- **Class based on Risk associated with the vulnerability of the human body, the technical design and manufacture of devices**
- **In the EU medical devices regulations, both options have been used:**
  - **MDD: by rules (Annex IX: classification rules)**
  - **IVD: by lists (Annex II: lists A and B)**
  - **AIMD: all devices have a similar risk, classification is not necessary**

Classification by rules in the MDD

- System defined in Annex IX of MDD
- 4 classes: I, IIa, IIb, III
- Use of classification criteria
- A set of 18 rules is used, plus several application rules
  - 4 rules for non-invasive devices (including one rule for wound care devices)
  - 4 rules for invasive devices
  - 4 additional rules for “active” devices (both non-invasive and invasive)
  - 6 “special rules” for the exemptions
- Vulnerability depending upon:
  - intended use / duration of use / part of human body

Classification criteria

- **Invasiveness:**
  - non invasive
  - invasive by body orifices
  - surgically invasive
  - implantable
- **Duration of use:**
  - transient (up to 60 min.)
  - short term (up to 30 d)
  - long term (above 30 d)
- **location of use:**
  (vulnerability of body part)
  - central nervous system
  - central circulatory system
  - in the teeth
  - in the ear up to ear drum
  - for blood
  - other parts of the body

Classification criteria (cont'd)

- **energy supply need** - "non active"
  - "active"

  (see definition "active medical device")

- **risk of the procedure:** - potentially dangerous
  - not potentially dangerous

Application rules

- The combination of various classification criteria leads to a certain class
- More than one rule might apply: then the highest resulting class counts
- Accessories may be classified separately from the basic device
- Software belongs to the same class as the device it is used for

Classification example: Tongue depressor

- **Criteria:**
  - **Invasiveness “invasive in natural body orifice”**
    - combined with
  - **Duration of use “transient”**
    - combined with
  - **“non active, and not intended to be connected to an active medical device”**

- **leads to class I.**

Classification example: Urethral catheter

- **Criteria:**
  - **Invasiveness “invasive in natural body orifice”**
    - combined with
  - **Duration of use “short term”**
    - combined with
  - **“non active, and not intended to be connected to an active medical device”**

- **leads to class IIa.**

Classification example: Blood Bag

1. **Not considering needle**

- **I. Non-invasive devices**
  - **1.1 Rule 1**

    All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

Rule 1 => Class I (sterile)

Classification example: Blood Bag

- **1.2. Rule 2**

  All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa […]

~~Rule 1 => Class I (sterile)~~

Rule 2 => Class IIa

Classification example: Blood Bag

- 1.3. Rule 3

  All non-invasive devices intended for modifying the biological composition of blood, ….

- 1.4. Rule 4

  All non-invasive devices which come in contact with injured skin …

~~Rule 1 => Class I (sterile)~~

Rule 2 => Class IIa

Classification example: Blood Bag

2. Blood Bag with needle

- 2. Invasive devices
  - 2.1. Rule 5

    All invasive devices with respect to body orifices ...
  - 2.2. Rule 6

    All surgically invasive devices intended for transient use are in Class IIa unless they are: [...] (needle)

~~Rule 1 => Class I (sterile)~~

Rule 2 => Class IIa

Rule 6 => Class IIa

Classification example: Blood Bag

- **2.3. Rule 7**

  All surgically invasive devices for short term use are in class IIa unless they are intended ...

- **2.4. Rule 8**

  All implantable devices and long term surgically invasive devices are in Class IIb unless they are: […]

~~Rule 1 => Class I (sterile)~~

Rule 2 => Class IIa

Rule 6 => Class IIa

Classification example: Blood Bag

- 3. Additional Rules applicable to active devices
  - Rule 9 – 12
    active therapeutic devices, active devices intended for diagnosis, active devices intended to administer energy / medicines, other active devices

~~Rule 1 => Class I (sterile)~~
Rule 2 => Class IIa
Rule 6 => Class IIa

Classification example: Blood Bag

- 4. Special Rules
  - Rules 13 - 18,
    special rules for devices which would otherwise be in a too low class: Drug/Device combination (13, III), contraception (14, IIb), contact lense care (15, IIb), disinfectant (15, IIa), X-ray imaging (16, IIa), animal tissue (17, III),
  - Rule 18
    By derogation from other rules blood bags are in class IIb

~~Rule 1 => Class I (sterile)~~

~~Rule 2 => Class IIa~~

~~Rule 6 => Class IIa~~

Rule 18 => Class IIb

Some rules of thumb

- Many non-active external devices are class I
- Most invasive devices are class IIa
- Most devices for heart, central circulatory and central nervous system are class III
- Contraceptive devices class IIb
- General disinfecting devices of MD class IIa
- Most implants are class IIb
- Many electro-medical devices are class IIa or IIb
- Drug-device combinations / non-viable animal tissues are class III
- Guide wires class III

Responsibilities

- Manufacturer is responsible for classification, based on the intended use specified by him
- A Notified Body (if involved) may challenge manufacturer's classification
- A Notified Body could reject a contract if it does not agree with manufacturer's classification
- Manufacturer and NB may seek advice from Competent Authority
- Classification rules may be modified by the CEC

Conclusions

- System is in operation since 1995
- Sometimes little difficulties,
  but no basic problems
- Always actual
- One minor modification of system by CEC: Breast implants now class III
- Further minor modifications pending
  (some joint implants)

Thank you!

Lars-Oliver Huber
Operations-Director Pacific\Korea
Medical – Health – Sports
TÜV Product Service Japan Ltd.