NSAI Certification

Irish Decontamination Institute Annual Conference 2012

Where do we fit in: The Medical Device Directive

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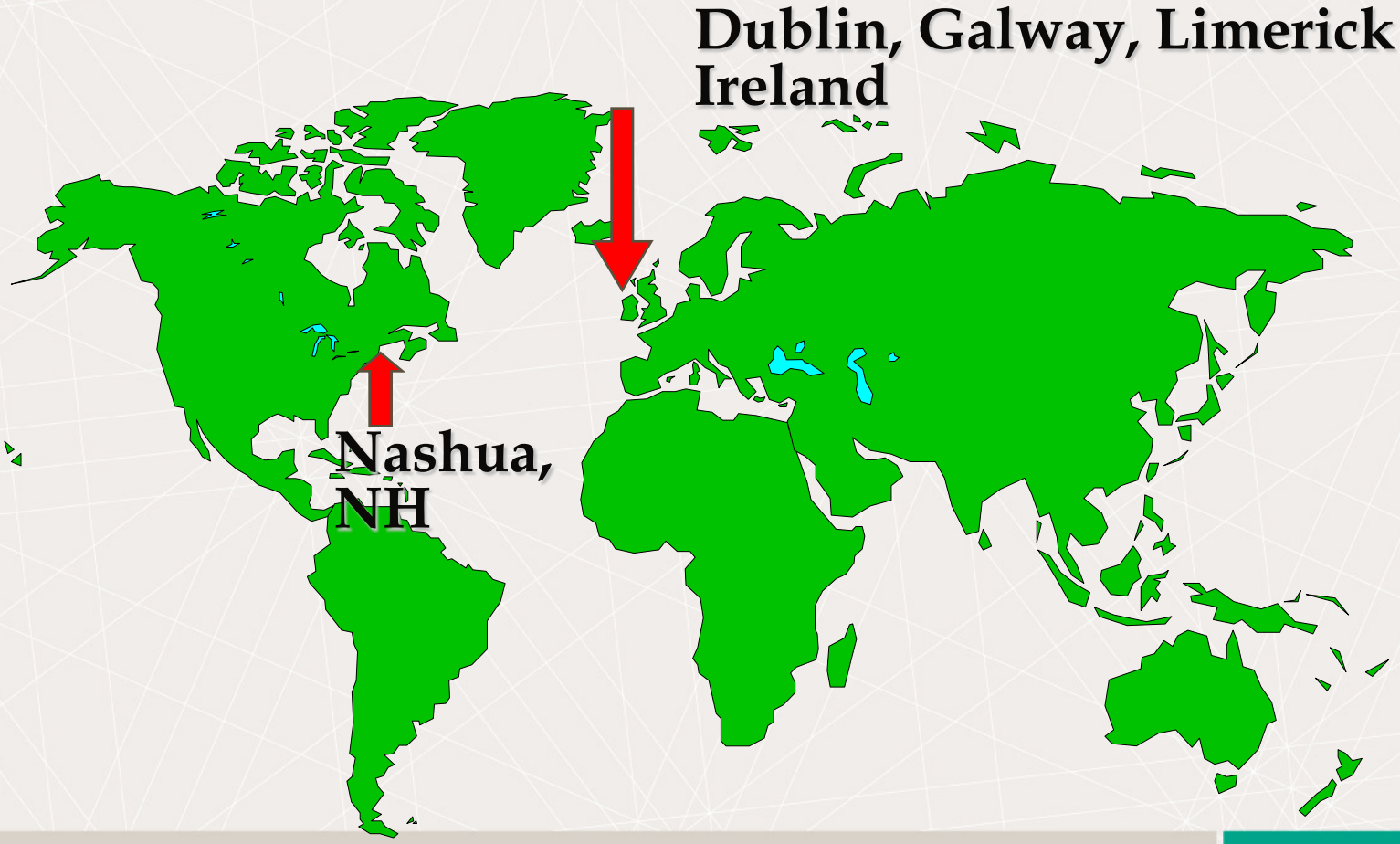
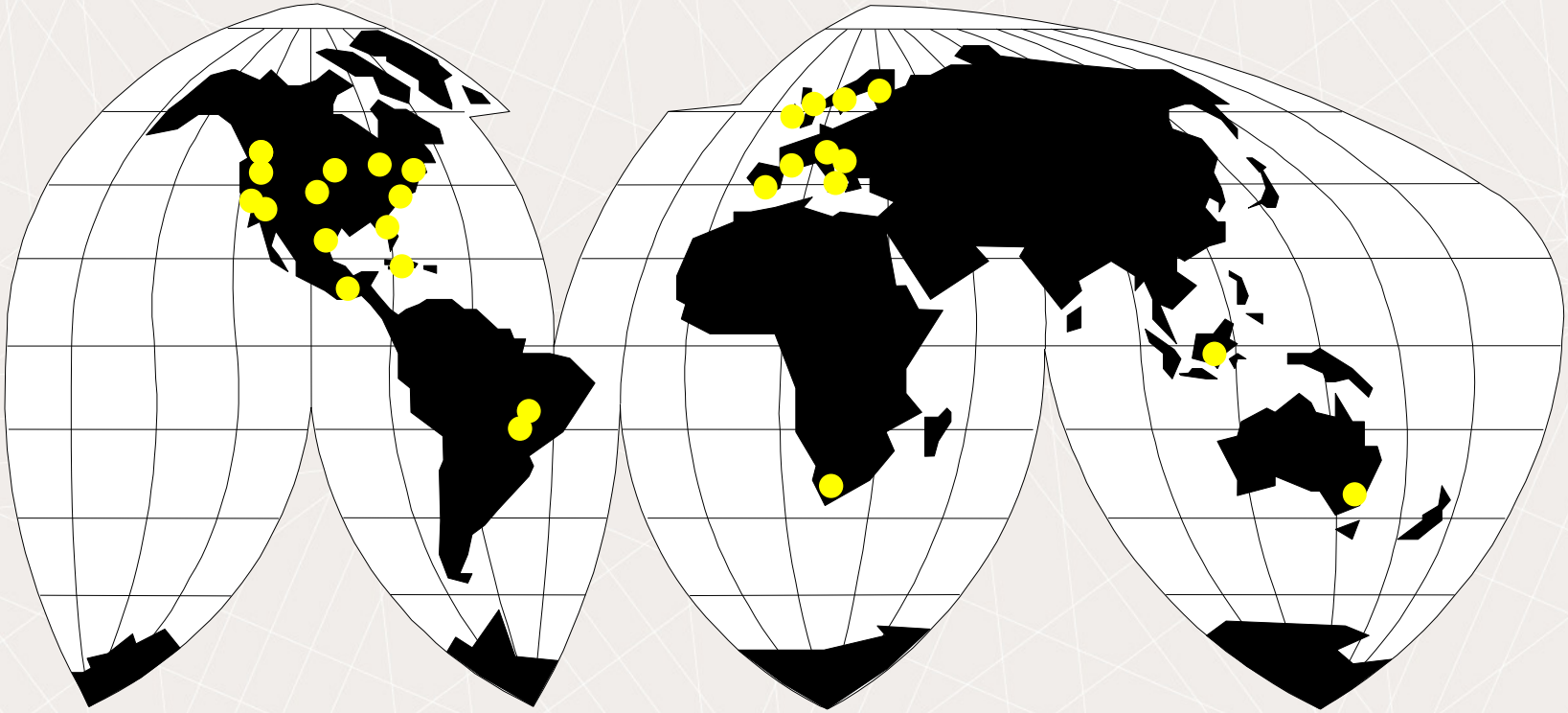
2nd November 2012

National Standards Authority of Ireland – Office Locations



National Standards Authority of Ireland – 3,000+ Registered / Certified Firms



➔ Carry out in excess of 6,000 assessments per year

National Standards Authority of Ireland – Overview

Provides QMS Certification

- NSAI are accredited to
  - ISO 17021 by INAB & UKAS for ISO 9001:2008
  - ISO 13485 & CMDCAS requirements by ANAB
  - ISO 14001 by ANAB (ANSI-ASQ National Accreditation Board)

- Certification activities cover the following areas
  - Medical Devices
  - Agrément
  - Automotive
  - Timber Certification

- NSAI is the National Standards development body – participates in development for national and European stds

National Standards Authority of Ireland – Medical Device Notified Body

NSAI is designated by the Irish Medicines Board (IMB) for the following Directives

- **MDD 93/42/EEC**
  - Annex II, V & VI
- **AIMD 90/385/EC**
  - Annex II & V
- **HUMAN BLOOD 2000/70/EC**
- **TSE 2003/32/EC**
- **IVDD 98/79/EC**
  - Annex III, IV & VII
  - Annex II List B Products
  - Self Test devices
    - Blood Sugar
    - General immunology
    - General haematology
    - General chemistry

Medical Devices Directives - Purpose

- Purpose of Directives is to harmonise controls to regulate the safety and performance of medical devices throughout the EU
- Outlines explicit obligations for manufacturers who intend to place their products on the European market
- They are intended to prohibit the marketing of devices, which may compromise the health and safety of patients and users

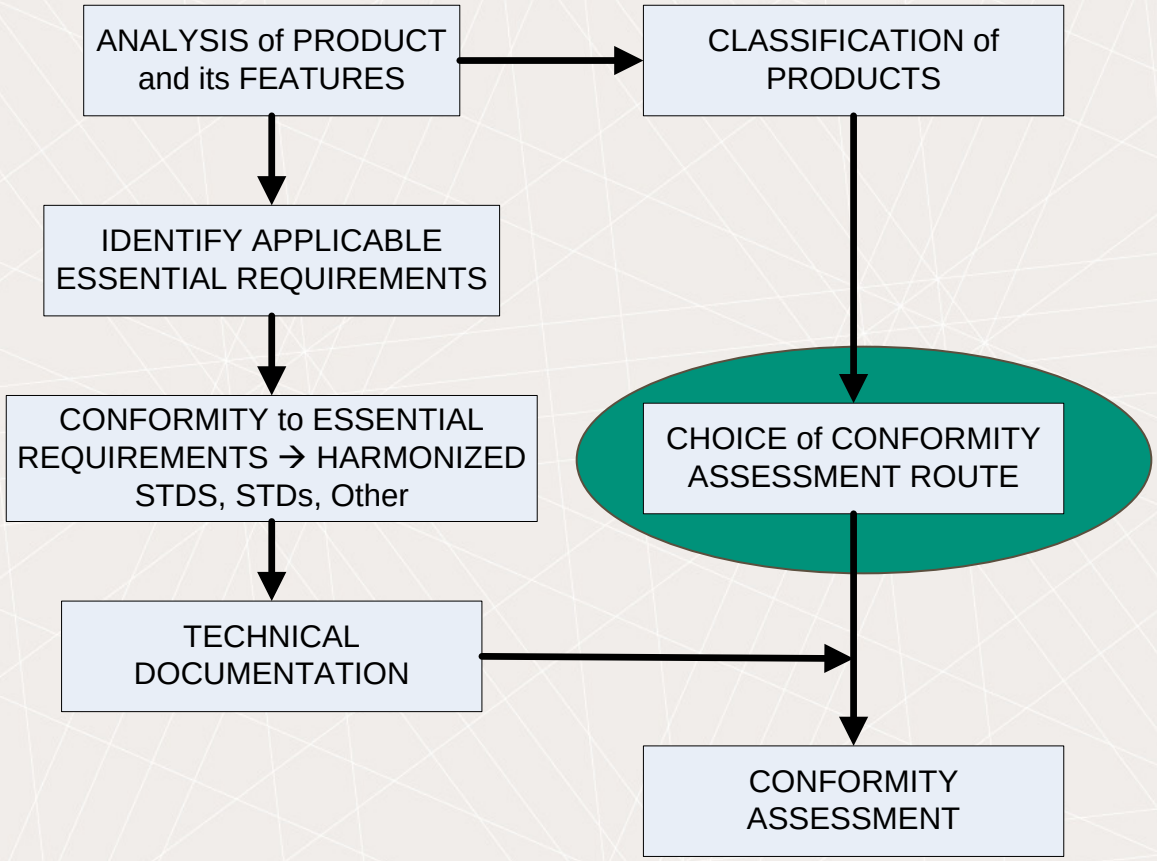
Medical Devices Directives - Key Elements

- All devices (except Class 1/Custom Made Devices) go through a Conformity Assessment to show compliance with the Legislation / Directive
- Specific list of “Essential requirements” (ER’s) that must be met
- Controls for the safety, performance, design, manufacture and packaging of devices are outlined
- Requirements for the assessment of Clinical Investigations, and the evaluation of any adverse incidents that occur;
- Introduces a classification system whereby the applicable controls are proportional to the inherent risk of the device
- All activities to be completed within a Quality Management System (Recognized standard for Med Dev Ind – ENISO13485)

NSAI Certification

How does a Manufacturer place a Medical Device on the European Market

Product Approval – Basic Approach



CE 0050

Product Approval
– Conformity Assessment Routes

For MDD 93/42/EEC

- Annex II Full QA System
- Annex III EC Type Examination
- Annex IV EC Verification
- Annex V Production Quality Assurance
- Annex VI Product Quality Assurance
- Annex VII EC Declaration of Conformity

Product Approval – Conformity Assessment Routes

Annex II Full QA

- **Approval of Site Quality System (Incl Design)**
- **Design Dossier Approval***
- **Technical Documentation**
- **Approval for Application of Product Concerned**
- **Declaration of Conformity**
- **Affix CE Marking**

Annex V Production QA

- **Approval of Site Quality System (Excl Design)**
- **Technical Doc (Annex III/V & V/VII)***
- **Approval for Application of Product Concerned**
- **Declaration of Conformity**
- **Affix CE Marking**

Annex VI Product QA

- **Approval of Site Quality System (Excl Design)**
- **Technical Doc (Annex III/VI & VI/VII)***
- **Approval for Application of Product Concerned**
- **Declaration of Conformity**
- **Affix CE Marking**

NSAI Certification

** - Depends on the classification of the Device concerned*

I.S. EN ISO 13485

Medical Devices – Quality Mgmt Systems

- **ISO 13485**
  - Current edition – EN ISO 13485:2012 (Aug 2012)
  - Previously based on EN ISO 13485:2003, EN ISO 13485 & 13488:2000 / Prior to this EN 46000 series

- **Link to Directives**
  - Directives don't mention standards
  - Reference to "harmonised standards" as a means of meeting requirements
  - EN ISO 13485:2012 is Harmonised standards
  - Article 5 – Use of Harmonised standards ➔ Presumption of conformance

- **Process Based Structure**

I.S. EN ISO 13485
- Process Approach

- **Process Characteristics**

- Has an owner
- Is defined
- Is documented
- Has linkages
- Is monitored
- Is recorded
- Has an Input
- Has an output

I.S. EN ISO 13485
- Process Approach

- Each individual process is mapped (input, activity, output)
- All appropriate areas of the standard is identified for each process

I.S. EN ISO 13485
- Process Approach

With What 6.3, 6.4, 7.5.1, 7.6

Production Equip
Tooling
Handling Equip
Measurement Equip
Facilities/ Environment

With Who 6.2

Competent: Operators
Inspection
Supervision
Key skills

7.4, 7.2

Schedule
Materials
Tooling

Input

Production Processes

Output

5.2, 8.2.1

Product to spec
Meets customer requirements

Measurement 8.2.3, 8.2.4, 8.3, 8.4

Quantity / Quality
PPM / Scrap
Rework
Up Time / Down time
OTD

How 7.1, 7.5, 4.2.4

Process controls
Procedures
Work instructions
Quality plan
Records

I.S. EN ISO 13485
- Auditing

- Conformance to ISO 13485 and the relevant MDD, is assessed by certification body NSAI through a number of audit phases
- If compliance is demonstrated NSAI will make a positive recommendation
- If Conformance is not demonstrated NSAI and client will work together to close identified gaps
- Conformance to ISO 13485 does not automatically constitute conformity with national or regional regulatory requirements

I.S. EN ISO 13485

- NSAI Comments

For new companies (with limited knowledge of EN ISO 13485) NSAI provide and recommend completing the “Pre-Assessment Audit” option:

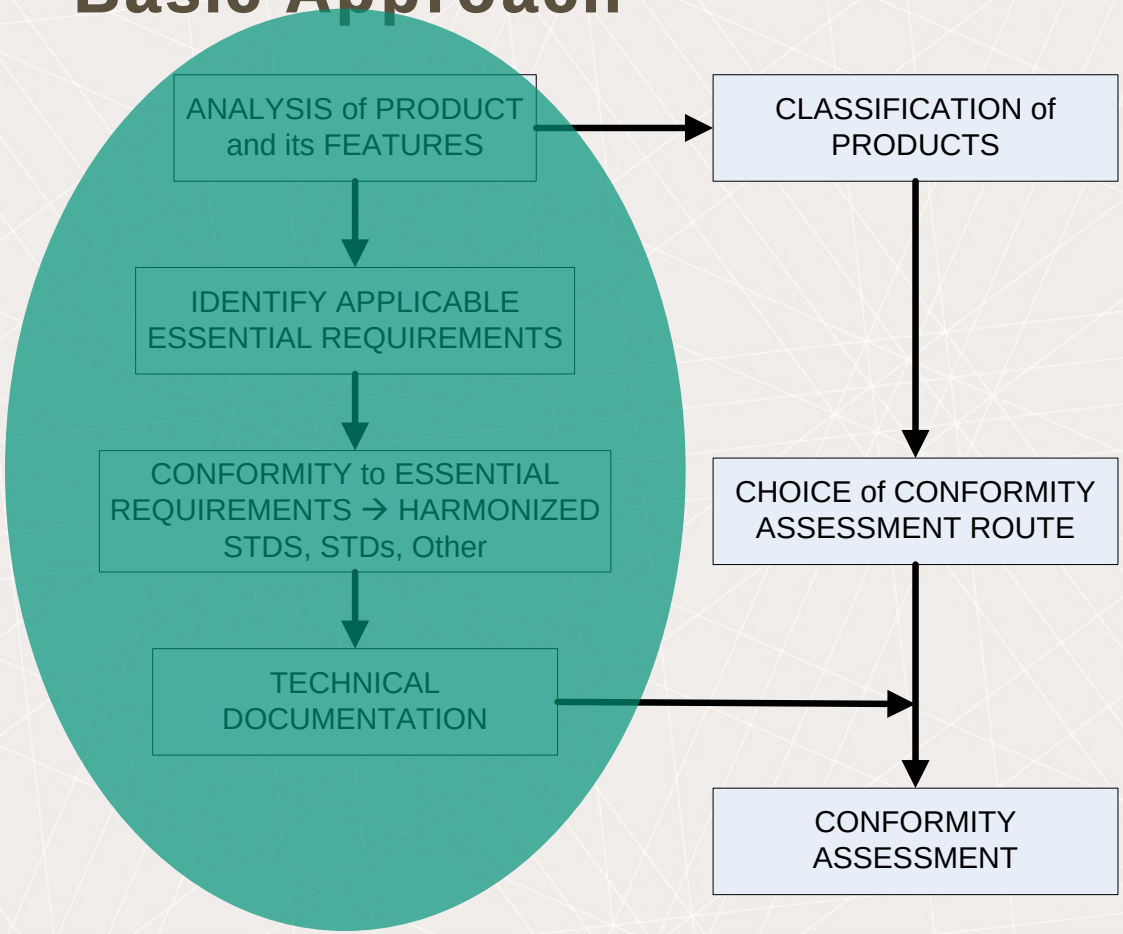
- Pre-assessment audit stresses the QMS versus the standard
  - Weaknesses are identified
  - Issues are not categorised as non-conformances & do not influence the registration audit
  - Client may ask questions of the auditor

I.S. EN ISO 13485
- NSAI Comments (cont'd)

- Pre-Assessment audit shall set clear expectations for the registration audit as the auditor shall more than likely complete the registration audit also

- NSAI will not execute a registration audit w/o
  - At least 3 months of data
  - Full round of Internal Audits completed
  - Management Review Completed

NSAI Product Approval
- Basic Approach



NSAI Product Application

- What does Notified Body review

- Certification details for design sites, manufacturing & assembly sites and sterilisation facilities, including details of their registered scopes
- Description of device and intended use
- Device Classification and followed Conformity Assessment Route
- Labelling
- Review of Risk Management file – identified, evaluated, controlled, accepted

NSAI Product Application

- What does Notified Body review

- Sterilisation Dataset – Validation reports to substantiate devices are sterile and comply with relevant harmonised standards *(EN ISO 11135-1:2007, EN ISO 11737-1:2006, etc)*
- *Biocompatibility Dataset* - Validation reports to substantiate devices are sterile and comply with relevant harmonised standards
- Design Verification/Validation Data – Output of development process meets product requirements and proposed Intended Use (Bench, Animal, Clinical data)
- Declaration of Conformity

NSAI Certification

Healthcare Institution Considerations

- Quality Management System
- CE Marking

Healthcare Institutions
- MDD definitions for Consideration

The MDD defines the Legal Manufacturer as:

- The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is ***placed on the market*** under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

- The obligations of this Directive to be met by manufacturers ….who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being ***placed on the market*** under his own name.

Healthcare Institutions
- MDD definitions for Consideration

- ‘Placing on the market’ refers to the ‘... first making available in return for payment or free of charge of a device . . . . with a view to distribution and/or use on the Community market....’

Healthcare Institutions
- Legal Manufacturer Under Regulations

- When Medical devices are manufactured by a healthcare institution, they will either remain within that legal entity or be transferred to a different legal entity (hospital, clinic, GP practice etc)

- **Consider whether your institution is a single legal entity or is it part one of a number of institutions covered under the umbrella of a legal entity**

Healthcare Institutions

- Transferring to another Legal Entity

Where a:

- Healthcare institution manufactures a device with intention of marketing them to another legal entity
- Healthcare institution manufactures a device and gives away FOC

These activities fall within the scope of the directives and the requirements of the Medical Devices Regulations must be met; these devices must comply with all the relevant essential requirements and the Healthcare Institution is defined as a ***Legal Manufacturer***

Healthcare Institutions

- Transferring to another Legal Entity

Included within this scope are:

- Those entities involved in assembly of systems and procedure packs
- Fully Refurbished devices
- The manufacture of splints by occupational therapists or physiotherapists for patients leaving a hospital
- Other examples – foot orthotics, pressure relief cushions and positioning devices, which leave the institution

Healthcare Institutions

- Remaining within Legal Entity

- If a device is made by one legal entity for use in or by patients of that same entity, there is no ***placing on the market*** and the Regulations do not apply - this is considered as “in house manufacturing” that falls outside the scope of the legislation

- Simple re-sterilisation of devices following the manufacturer’s guidelines e.g. surgical instruments, does not fall within the scope of the Regulations, ***unless you combine that product in a system and procedure pack for transfer to another legal entity***

Healthcare Institutions

- Sample Activities (Adapt, Modify, Refurbish)

- Adapt or Modify Devices

  Regulations may apply, Institution may be the legal manufacturer if the activity is significant enough to question the Safety and Performance of the device and hence void the original CE mark, and places it on the market

- Refurbish Devices

  Refurbishers are considered Legal Manufacturer as the device is stripped back and place back on market “As New”

  (Refurbishment is not routine cleaning)

Healthcare Institutions

- Sample Activities (Reprocessing)

Manufacturers of CE marked, reusable medical devices are required to provide 'information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized

Typical information supplied (varies depending on device complexity)

- Cleaning Instructions – dismantle, cleaning agents, accessories
- Disinfection Instructions – compatible disinfectants / equipment
- Sterilisation – method / cycle parameters
- Restrictions, if any, on the number of reuses

Healthcare Institutions
- Sample Activities (Reprocessing)

Effective reprocessing of reusable medical devices is essential in minimising the risk of transmission of infectious agents

(Note: Processing of supplied Non-sterile devices)

Sample Requirements would include:

- Documentation practices & procedures controlled
- Procurement policies in place regarding device compatibility with available decontamination processes
- Equipment to be validated/calibrated
- Monitored preparation area – particulates/microbiological
- Traceability and training

EN ISO 13485 Provides for this control and Traceability

Healthcare Institutions

- Practical Example

A Sterile Service Dept (SSD) providing a sterile instrument service to a private hospital, GP, or other institution under a different legal entity, would be regarded as placing a device on the market

- This activity would fall within the scope of the Regulations
- Institution considered a Legal Manufacturer and requires:
  - QMS
  - Scientific data to support safety and performance
  - Device approval through NB
  - Affixes CE Mark
  - Places device on the market

Healthcare Institutions

- Practical Example

If devices are supplied by an SSD for use on patients in that same healthcare establishment (same legal entity)

- This is not seen as ‘placing on the market’
- The Regulations would not apply
- Institute shall have documentation and procedures in place to provide control and traceability for the process

Healthcare Institutions

- Practical Example

Single Use Devices (SUD's)

- Have not been validated for reuse
- Will include a "risk of reuse statement" within the accompanying documentation
- If a Healthcare Institution reprocesses an SUD they shall generate and have available all relevant technical/scientific data to substantiate its safe use/performance – bench testing, risk management, sterilization validation, etc

Healthcare Institutions

- Overall Considerations Activities v MDD

1. What are our Activities?
2. Do these activities take place within one legal entity
3. When reprocessing, are the devices reusable / are there any restrictions to reprocessing
4. Are we following the instructions supplied with the devices
5. Do we have documented procedures in-place for processing of devices supplied non-sterile & for reusable devices
6. Do we fall under the definition of a *Legal Manufacturer*
7. Do we need to CE mark devices under a certified QMS

Collaborative Approach

- Site and Product Certification

Any Questions?

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