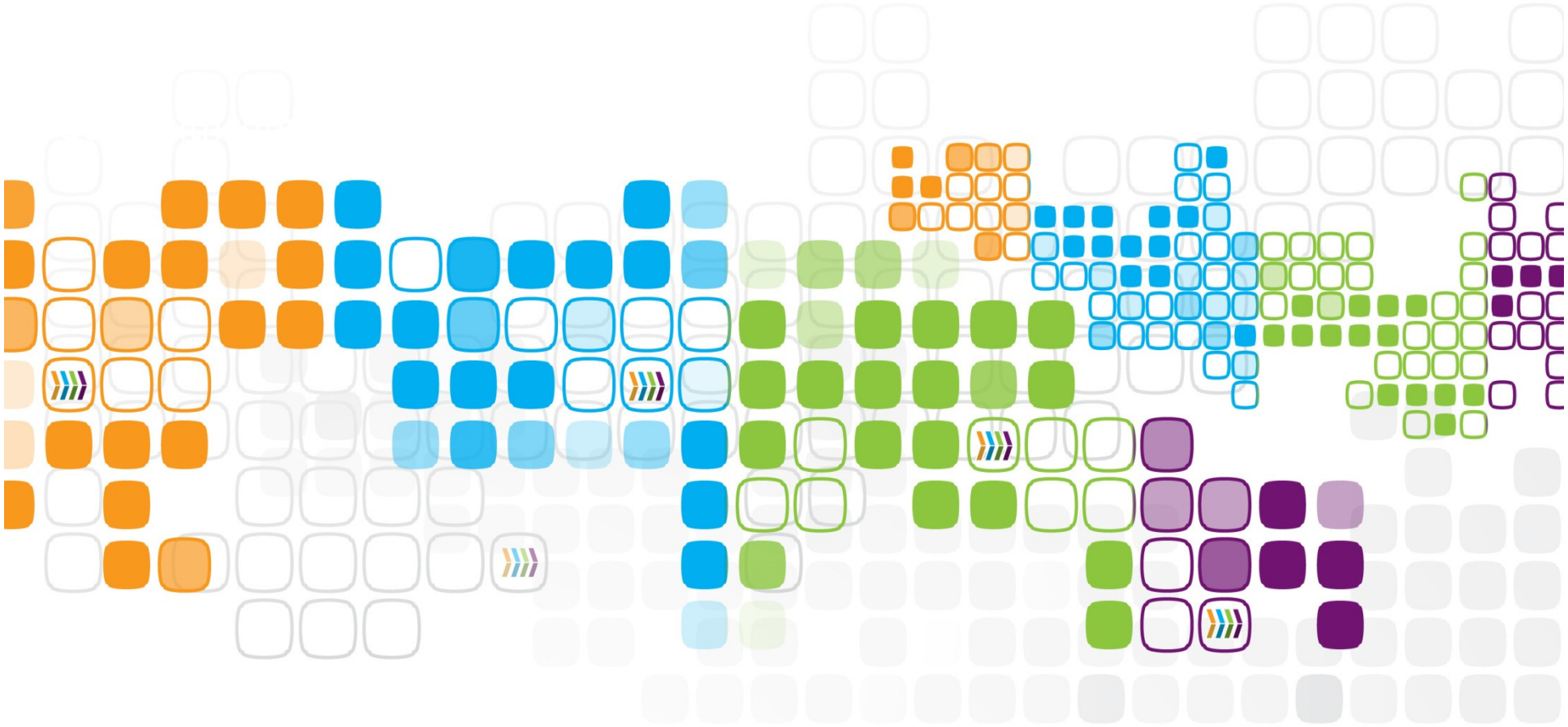


Regulatory Framework for Control of Refurbished Medical Devices

Alfred KWEK
Director, Regulatory Affairs, ASEAN
GE Healthcare
Presentation to APEC Workshop on Remanufactured Goods, Malaysia, 22 Oct 2012

GE Today

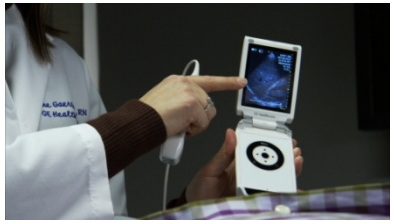
GE Energy

Oil & Gas

Energy Management

Power & Water

Healthcare



Aviation

Transportation

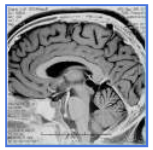
GE Capital

Home & Business Solutions

$147B Revenue - Only current DJIA company in original index – 300,000 employees - Named one of the World's Most Ethical Companies by Ethisphere in 2007, 2008, 2009, 2010, and 2011

$18B Broad Technology Portfolio

Diagnostic & Clinical Equipment



Diagnostic Imaging

Clinical Products

Home Health

Information Tech. and Services

Electronic Medical Records (EMR)

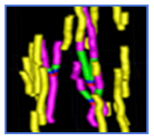
Picture Archiving System (PACS)

Clinical Knowledge solutions

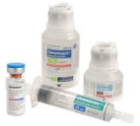
Equipment Service Solutions

Molecular Medicine

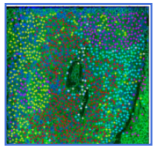
Bio-process



Protein & Cell Sciences



Contrast Media



Molecular Pathology


HEALTHCARE
TOUCHES
EVERYONE
COST
QUALITY
ACCESS
healthymagination
imagination at work

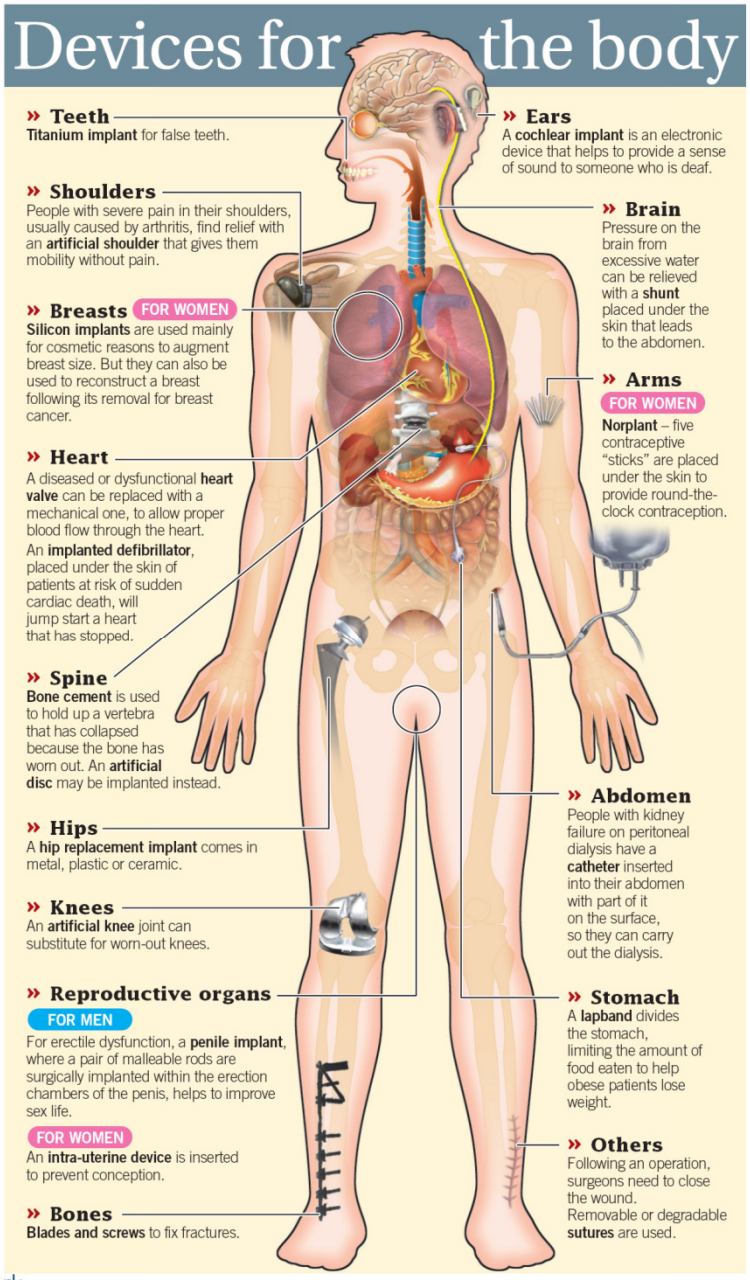
Agenda

- What is a medical device?
- What is / not Refurbishment?
- Ensuring Safety of Medical Device

  Manufacturers

  - Quality Management System
  - Use of International Standards to Ensure Safety & Performance
- Ensuring Safety of Refurbished Medical Device

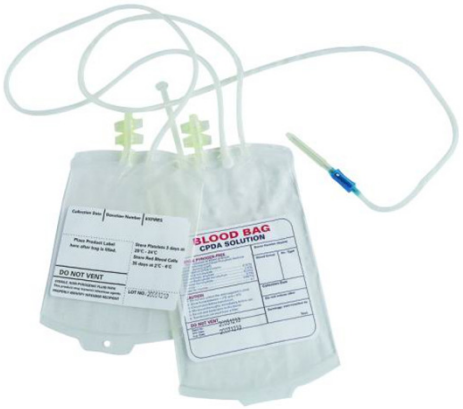
GE imagination at work



Medical Devices: Spare Parts for Ourselves

Examples of medical devices

- Bandages
- Gauge
- IV Sets
- Blood bags
- Wheel Chair
- Hospital bed



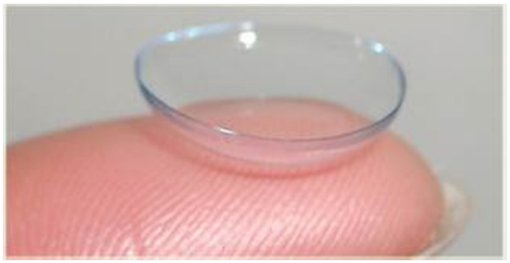
Examples of medical devices

Non-medicated saline eye wash

Examination gloves

Contact lenses for long- term continuous use

Tracheal tubes

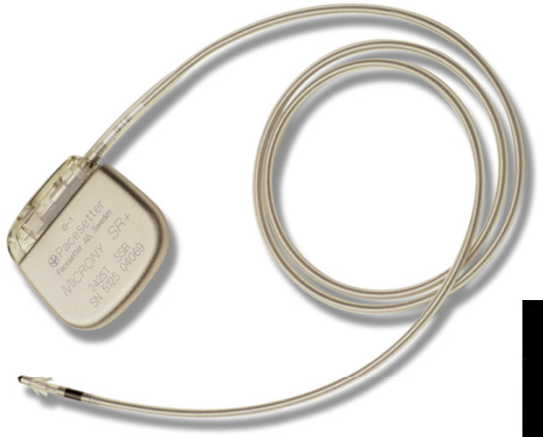


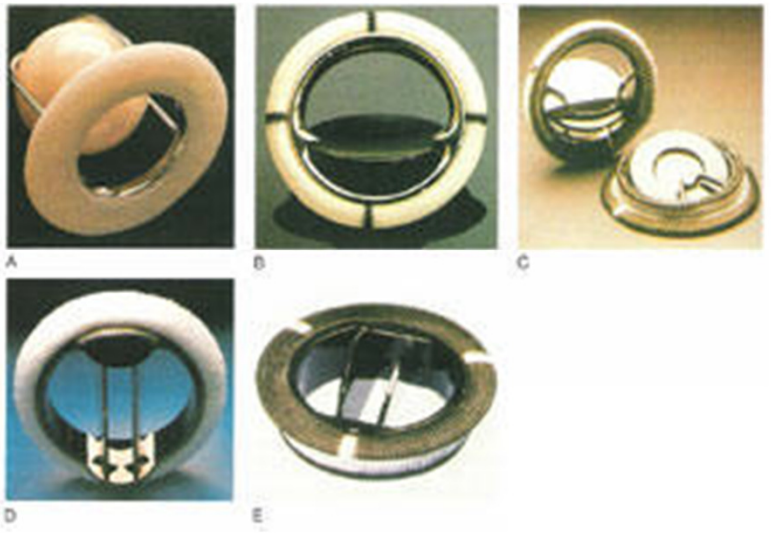
Examples of active devices

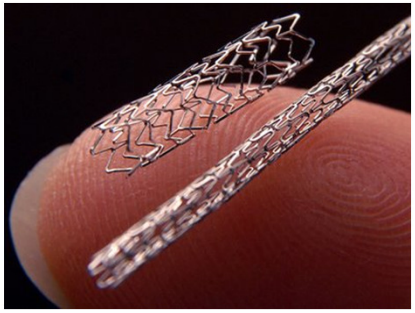
- Hearing aids
- Baby incubator
- CT Scanner
- Electronic thermometer

Examples of implants and long term invasive devices

- Prosthetic heart valves
- Pacemaker
- Stents
- Breast implants







Definition – Medical Device

"medical device" shall mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent and calibrator, software, material or other similar or related article:

(a) intended by the product owner to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

(iii) investigation, replacement, modification, or support of the anatomy or of a physiological process,

(iv) supporting or sustaining life,

(v) control of conception,

(vi) disinfection of medical devices,

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Refurbishment versus Single Use

Refurbishment	Single Use
Applies mainly to reusable devices.	Single use devices are, by definition, normally used in their original state, then discarded
	

Not every medical device is appropriate for refurbishment

Repair and Maintenance

It is common for a reusable medical device to require routine service and repair in order to maintain it in good and safe operating condition.

Such repair and maintenance may be carried out by the owner, the manufacturer or a third party.

Repair and maintenance is not refurbishment

Medical Device Regulatory Framework

Figure 6. Common stages of government regulations

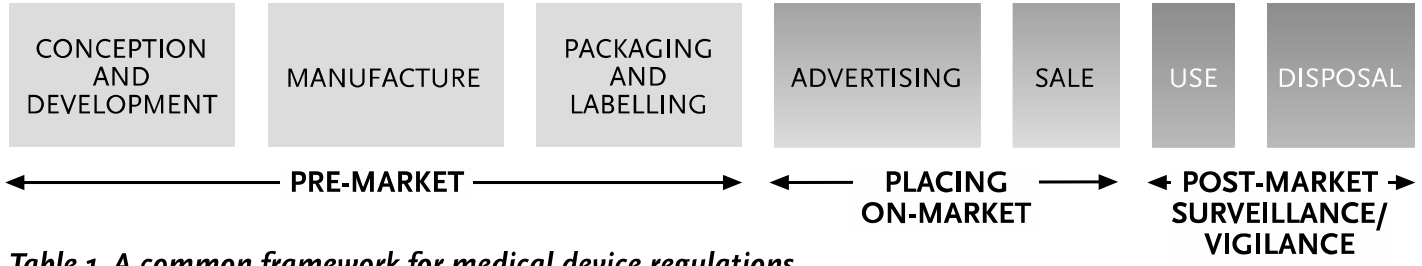


Table 1. A common framework for medical device regulations

STAGE	PRE-MARKET	PLACING ON-MARKET	POST-MARKET
CONTROL/MONITOR	PRODUCT	SALE	AFTER-SALE/USE
PERSON	MANUFACTURER	VENDOR	VENDOR/USER
Items or activities regulated	**Device attributes** • Safety and performance **Manufacturing** • Quality systems (see 3.4.4) **Labelling** (representation) • Accurate description of product • Instructions for use	**Establishment registration** • List products available or in use • Requires vendor to fulfil after-sale obligations **Advertising** (representation) • Prohibits misleading or fraudulent advertisement	**Surveillance/vigilance** • After-sale obligations • Monitoring of device's clinical performance • Problem identification and alerts

Source: WHO, medical device regulations: global overview and guiding principles (2003)

Definition (draft AMDD)

REFURBISHED MEDICAL DEVICE:

a medical device of which the whole or any part thereof has been substantially rebuilt, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the **purpose** originally intended by the product owner of the original medical device, and which may have had the following work carried out on it:

- stripping into component parts or sub-assemblies;
- checking their suitability for reuse;
- replacement of components/sub-assemblies not suitable for reuse;
- assembly of the reclaimed and/or replacement components/sub-assemblies;
- testing of the assembled device against either original or revised release criteria; or
- identifying an assembled medical device as a refurbished medical device.

*Source: Annex 9 Labelling Requirements of the **DRAFT ASEAN Medical Device Directive***

GHTF* Definition of a Manufacturer

Any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies)

*Global Harmonization Task Force

GHTF Definition of a Manufacturer

This natural or legal person has the ultimate responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold

Manufacturer's responsibilities described in other GHTF guidance documents – include pre- and post- marketing requirements (e.g., vigilance reporting and notification of field safety corrective actions)

GHTF Definition of a Manufacturer

Design and/or manufacture may include:-

- Specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilisation, installation, or remanufacturing; and/or
- Assembly, packaging, processing and/or labelling of one or more finished products

GHTF Definition of a Manufacturer

Any person who assembles or adapts a device(s) that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is **not** the **manufacturer**, provided the assembly or adaptation **does not change the intended use** of the device(s)

GHTF Definition of a Manufacturer

Any person who **changes** the **intended use** of, or modifies, a **finished medical device** in a way that may affect **safety or performance**, without acting on **behalf of the original manufacturer** and who makes it available for use under his own name should be **considered the manufacturer** of the **modified** medical device

Parties Involved

Authorised Refurbisher

- Work with manufacturer specifications
- May include changes/upgrades
- Refurbishment done at request of original manufacturer and product re-sold by manufacturer

3rd Party Refurbisher

- Refurbish equipment without manufacturer's authorization
- "Refurbished" device is placed on the market under the name of the person responsible for the refurbishment, without changing the intended use
- Person responsible for the refurbishment = new product owner

If the intended use/purpose of the device is changed after "refurbishment" it is a "new" medical device.

Ensuring Safety of New Devices

(non-exhaustive)

GE imagination at work

LNE

Le progrès, une pensée à partager

Certification
Médical-Santé

ATTESTATION/ *CERTIFICATE* **N° 7854 rev 2**
Délivrée à Paris le 01 Décembre 2011
Issued in Paris on December 1st, 2011

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité */ Approval of full Quality Assurance System*
ANNEXE II point 3 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant (nom et adresse) */ Manufacturer (name and address)*

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd,
WAUKESHA, WI 53188 UNITED STATES

Catégorie du(des) dispositif(s) */ Device(s) category*

Dispositif ou système de radiodiagnostic

Medical diagnostic radiology device or system

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé M011885-R, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II point 3 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced M011885-R, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II section 3

Début de validité */ Effective date :* **December 21st, 2011 (included)**
Valable jusqu'au */ Expiry date :* **December 20th, 2014 (included)**

LABORATOIRE NATIONAL de METROLOGIE et d'ESSAIS

For the General Director
Laurence DAGALLIER
Deputy Director

LNE/G-MED CE **0459**

LNE - 7854 rev. 2
Renouvelle le certificat 7854-1

Laboratoire national de métrologie et d'essais - Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr

EC Certificate

- EC Certificate
- Approval full Quality Assurance System
- *Annex II section 3 Directive 93/42/EEC* concerning medical devices
- Manufacturer
- GE Medical Systems, LLC – Waukesha, WI 53188, USA
- Device category
- Medical diagnostic radiology device or system
- G-Med certifies that, on the basis of the results contained in the file referenced M011885-R, the *quality system* – for design, manufacturing, and final inspection – of medical devices listed here above *complies with the requirements of the Directive 93/42/EEC, annex II section 3.*

What's Does it Mean?

As an example

- What are the meanings behind the wordings of the certificate?
- Notified Body (CE XXXX) issues a certificate. It means that:-

  - manufacturer has maintained a QMS that meets the ISO 13485:2003 standard;

and

  - meets **EU Medical Device Directive (93/42/EEC)**

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-1-1

Deuxième édition
Second edition
2000-12

Appareils électromédicaux –

Partie 1-1:
Règles générales de sécurité –
Norme collatérale: Règles de sécurité pour systèmes électromédicaux

Medical electrical equipment –

Part 1-1:
General requirements for safety –
Collateral standard: Safety requirements for medical electrical systems

EU Harmonized Standards (Ionizing Radiation Devices)(New)

EN 60601-1-3:2008

Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance -

Collateral Standard: Radiation protection in diagnostic Xray equipment

IEC 60601-1-3:2008

EU Harmonized Standards (Ionizing Radiation Devices)(Old)

EN 60601-1-3:1994

Medical electrical equipment -- Part 1: General requirements for safety -- 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:1994

Refurbishment

GE imagination at work

Principles of **Good Refurbishment Practices (GRP)**

Refurbishment Definition

"a **systematic** process that ensures safety and effectiveness of the medical equipment **without** significantly changing the equipment's or system's performance, safety specifications and/or changing **intended use as in its original registration**".

Principles of **Good Refurbishment Practices (GRP)**

Any upgrades processed during GRP refurbishment shall be performed in a manner consistent with the **original product specifications** and **service procedures** defined by the **manufacturer** for that equipment or system.

Same Elements of Regulatory Control for MDs

- ✓ Quality Management System (QMS)
- ✓ Post-market Surveillance
- ✓ Technical Documentation
- ✓ Declaration of Conformity
- ✓ Registration of manufacturers, distributors and their devices

LNE

Le progrès, une passion à partager

Certification Médical-Secteur G-MED

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 7850 rev 4

Le LNE certifie que le système de management de la qualité développé par

LNE certifies that the quality management system developed by

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd,
WAUKESHA, WI 53188 UNITED STATES

pour les activités
for the activities

Conception, fabrication, contrôle final de dispositifs ou systèmes d'imagerie médicale.
Voir addendum

Design, manufacturing, final test of medical imaging devices or systems.
See addendum

réalisées sur le(s) site(s) de
performed on the location(s) of

GE MEDICAL SYSTEMS, LLC
3000 North Grandview Blvd - WAUKESHA, WI 53188 - UNITED STATES
GE MEDICAL SYSTEMS, LLC
3114 North Grandview Blvd - WAUKESHA, WI 53188 - UNITED STATES
GE MEDICAL SYSTEMS, LLC
4855 West Electric Avenue - MILWAUKEE, WI 53219 - UNITED STATES

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 9001 : 2008 - ISO 13485 : 2003

Début de validité / *Effective date :* **December 21st, 2011 (included)**
Valable jusqu'au / *Expiry date :* **December 20th, 2014 (included)**
Etabli le / *Issued on :* **December 1st, 2011**

LABORATOIRE NATIONAL de METROLOGIE et D'ESSAIS

For the General Director
Laurence DAGALLIER
Deputy Director

cofrac

LNE N° 7850-4
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification
LNE/G-MED Organisme notifié pour les Dispositifs Médicaux / LNE/G-MED Notified Body for Medical Devices

Renouvelle le certificat 7850-3

Laboratoire national de métrologie et d'essais - Établissement public à caractère industriel et commercial
LNE/G-MED - Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 - Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37 - www.lne.fr - www.gmed.fr

LNE
Le progrès, une passion à partager

Certification
Médical-Santé

Addendum au certificat N° 7850 rev 4 page 1 / 1
Addendum of the certificate N° 7850 rev 4
Dossier / *File* N° M011885-R

Résumé des activités couvertes par le certificat :
Summary of activities covered by the certificate :

French version :
Conception, fabrication, contrôle final de dispositifs ou systèmes de diagnostic tomodensitomètre par émission de positron, dispositifs ou systèmes de diagnostic X-Ray, dispositifs ou systèmes de diagnostic tomodensitomètres (scanners), gaines équipées (gaine + tube radiogène) et d'application logicielle.
Mise à disposition de dispositifs ou systèmes d'imagerie médicale d'occasion.

English version :
Design, manufacturing, final test of medical diagnostic positron emission tomography devices or systems, medical diagnostic X-Ray devices or systems, diagnostic computed tomography devices or systems, X-ray tube assembly (housing + tube) and software application.
Supply of pre-owned medical imaging devices or systems.

****

Certificate: ISO 13485:2003

- LNE certifies that the QMS developed by
- GE Medical Systems, LLC – Waukesha, WI 53188, USA
- for the activities – Design, manufacturing, final test of medical imaging devices or systems
- performed on the location - GE Medical Systems, LLC – Waukesha, WI 53188, USA
- complies with the requirements of the international standard ISO 13485:2003

- Summary of activities covered by certificate
- Design, manufacturing, final test of PET, X-Ray, X-Ray tube assembly and software applications
- Supply of pre-owned medical imaging devices or systems

- The quality management system is subject to yearly surveillance audit.

Medical Devices

Medical Device Safety

- Medical Device Recalls
- 2011 Medical Device Recalls
- 2010 Medical Device Recalls
- 2009 Medical Device Recalls
- 2008 Medical Device Recalls
- 2007 Medical Device Recalls
- 2006 Medical Device Recalls
- 2001 - 2005 Medical Device Recalls

List of Device Recalls

Search

SEARCH

Medical Device Recalls: Get e-mail updates

FDA posts consumer information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death.

Use the yearly lists to find information about Class I medical device recalls and some Class II and III recalls of interest to consumers. The links give details about what to do if you own or use one of these products.

Please note that FDA now lists medical device recall notices by the date that it posts the recall rather than the recall initiation date. You can find the date that a firm initiated a recall in the text of the recall notice.

Recent Medical Device Recalls

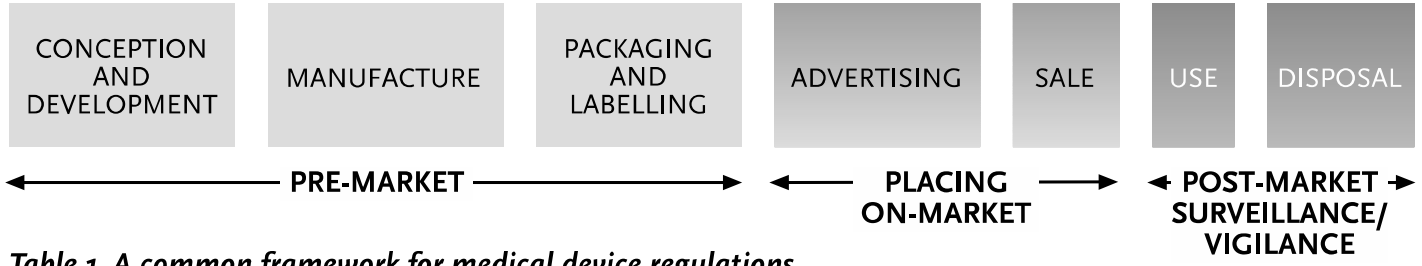
Listed by date posted on FDA website.

Device Name	Date
Custom Medical Specialties, Inc., Custom HSG Tray, Hysteroscopic Sterilization Pack, Custom Vein Tray, Custom Amnio Tray, Fox Chase Specials Pack, Abington Radiology Drainage Pack, Custom CT Biopsy Tray, HSG Tray, Custom Myelogram Tray, and Hysteroscopy Sterile Procedure Kit	09/25/12
I-Flow ON-Q Pump with ONDEMAND Bolus Button	08/31/12
Baxter Healthcare Corporation, Automix Automated Nutrition Compounder Systems	08/29/12
CareFusion Alaris Pump Module, Model 8100 – Motor Stall	08/23/12

Labelling of Refurbished Devices

Medical Device Regulatory Framework (Recap)

Figure 6. Common stages of government regulations



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Source: WHO, medical device regulations: global overview and guiding principles (2003)

Conclusion

- Ensuring Safety of New / Refurbished Medical Device

  Manufacturers & Refurbishers

  - Mfg / Refurbish to (Original) Intended Use
  - Subject to Audit of Quality Management System
  - Use of International Standards to Ensure Safety & Performance
  - Undertake Post market Surveillance and Vigilance activities (e.g. software / safety upgrades)

One yardstick for safety, quality & performance – "no double standard"

GE imagination at work

Thank You

(alfred.kwek@ge.com)

GE imagination at work