Asia-Pacific
Economic Cooperation

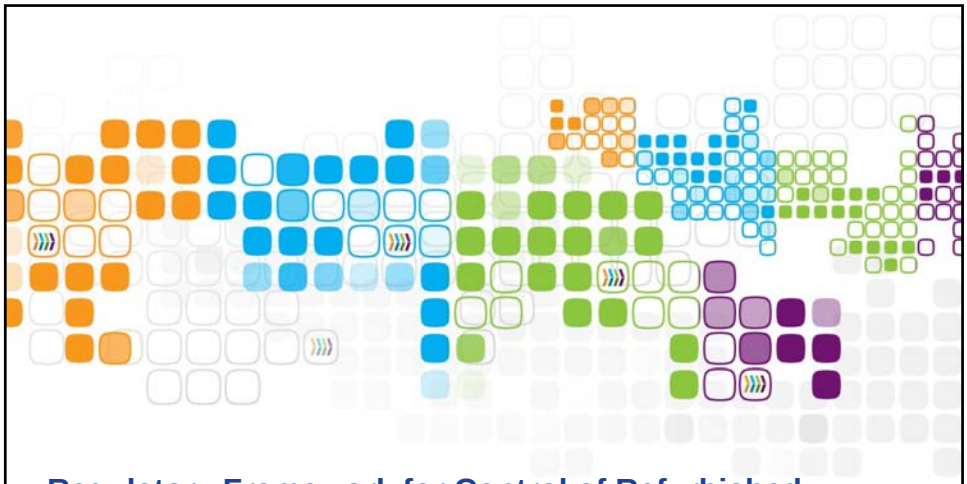
2012/CTI2/MAG/WKSP/011

Regulatory Framework for Control of Refurbished Medical Devices

Submitted by: GE Healthcare

APEC
RUSSIA 2012

Workshop on Remanufacturing Research and Development in APEC Economies
Singapore
28 March 2012



Regulatory Framework for Control of Refurbished Medical Devices

Alfred KWEK
Director, Regulatory Affairs, ASEAN
GE Healthcare
Presentation to APEC Remanufacturing Event, Singapore, 28 Mar 2012

CURICULUM VITAE

ALFRED KWEK

Presently, Director, Regulatory Affairs, ASEAN, GE Healthcare & Co-Chair, Asian Harmonization Working Party Work Group 1 on harmonizing pre-market registration requirements across Asia and Middle East

Prior, 7.5 years in Health Science Authority Singapore, last appointment as Deputy Director, Licensing & Surveillance, Medical Device Branch

- Part of Team that implemented Medical Device Regulations, and introduced ASEAN CSDT & GDP, in Singapore;
- Co-Chair ACCSQ MDPWG;
- Chair, AHWP Technical Committee; and
- Member of Global Harmonization Task Force Study Group 1

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Agenda

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

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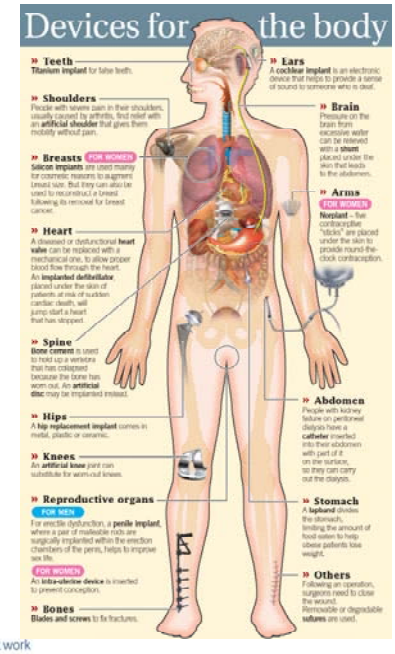

Medical Devices: Spare Parts for Ourselves

Copyright: The Straits Times, SPH

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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 economies 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

Ensuring Safety of New Devices

(non-exhaustive)

LNE
Le progrès, une passion à partager
Certification Médical-Santé

ATTESTATION/ *CERTIFICATE* N° 7848 - Revision 1
Délivrée à Paris le 8 décembre 2008
Issued in Paris on December 8th, 2008

ATTESTATION CE / *EC CERTIFICATE*
Approbation du Système Complet d'Assurance Qualité / *Approval 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 HANGWEI MEDICAL SYSTEMS CO.LTD
N°2, north yong chang street
Beijing Economic Tecnological Development Zone
BEIJING 100176
CHINA

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

Tomodensitomètres (scanners) - Systèmes d'imagerie par resonance magnétique
CT Scanners - MRI systems

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé J018084-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 J018084-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, 2008 (inclus)**
Valable jusqu'au / *Expiry date :* **December 20th, 2011 (inclus)**

LNE/G-MED CE 0459

For the General Director
Laurence DAGALLIER
Deputy Director

LNE – 7848-Rev 1
Renouvelle le certificat 0360/82P3/2

Laboratoire national de métrologie et d'essais - Etablissement 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

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EC Certificate

- EC Certificate
- Approval full Quality Assurance System
- *Annex II section 3 Directive 93/42/EEC* concerning medical devices
- Manufacturer
- GE Hangwei Medical Systems
- Device category
- CT Scanners – MRI systems
- G-Med certifies that, on the basis of the results contained in the file referenced J018084-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.*

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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)**

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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

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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

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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**".

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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

TÜV

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

**GE Medical Systems (China)
Beijing Branch
No. 1, Yong Chang North Road
Beijing Economic-Technological
Development Area**

**Beijing 100176
China**

has established and applies a quality management system for medical devices for the following scope:

Refurbishment and Service of CT, MR, XR Products (Gold Seal)

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60015780 0001
An audit was performed. Report No.: 15018565 001
This Certificate is valid until: 23.01.2012

Akkreditiert durch ZLG
ZLG-ZQ-955.00.01-46

Cologne, 24.01.2007

Certification Body
TÜV Rheinland Product Safety GmbH
TÜV Rheinland
Dipl.-Ing. D. Meier

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TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3933 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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GE Title or job number /
3/28/2012

Certificate: **EN ISO** 13485:2003

- Hereby certifies that the Organization
- GE Medical Systems (China)
- Has established and applies a quality management system for medical devices for the following **scope**
- **Refurbishment and Service of CT, MR, X Ray Products**
- Proof has been that the requirements specified in
- **EN ISO 13485:2003**
- are fulfilled. The quality management system is subject to yearly surveillance.

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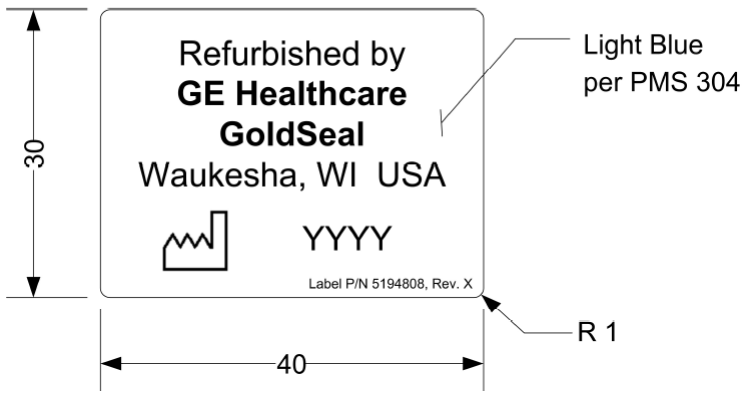
Labelling of Refurbished Devices



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Conclusion

- Ensuring Safety of New / Refurbished Medical Device

  Manufacturers / Refurbishers

  - Audit of Quality Management System
  - Use of International Standards to Ensure Safety & Performance

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

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Thank You

(alfred.kwek@ge.com)

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Conclusion

Global Harmonization Task Force

- What is GHTF & their current regulations?

Harmonization

- What is / what is not harmonization?

Tools of Harmonization – Common Dossiers, Grouping

- Tools to be used for registration
- Tools to be used for designing a regulatory framework that is least burdensome

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Conclusion

Tools of Harmonization – Common Dossiers, Grouping

- Use of international Standards / local standards)
- Outsourced / 3rd party manufacturing sites
- Clarity in grouping rules (affects registration fees)
- Grouping affects multi-economy use of CSDT
- Inclusion of accessories codes into CSDT (affects Import and supply of accessories)
- Import and supply of spare parts / expendables (affects local supply)

Conclusion

Recommendations

- Aware of need to map against other regulatory elements and guidance documents for setting up a harmonized regulatory framework (e.g. registration of manufacturers and listing of medical device, definition of MD, classification of MD, definition of manufacturers, authorized representatives)

Asia Network Design & Optimization (AsNDO)

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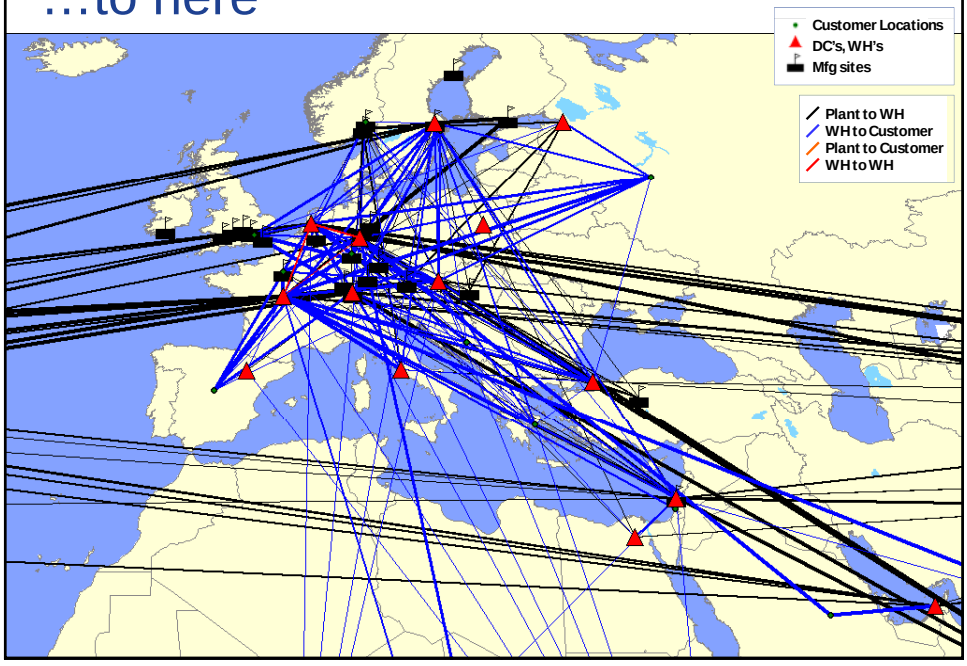
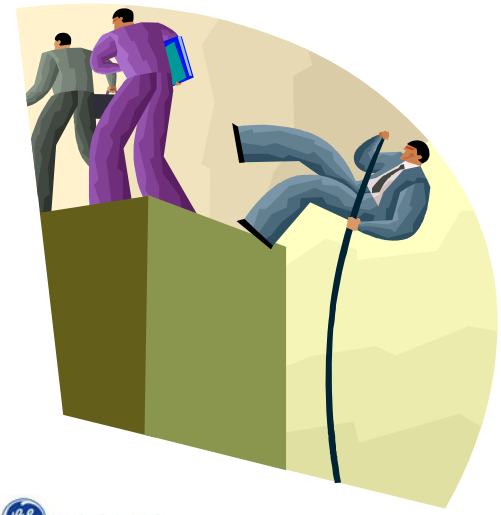


Overcome Current SC Challenges



1. Shortening product life cycles
2. Lengthening global supply chains
3. Increasing product complexity
4. Rising logistics expenses

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USA

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USA

Classification of Medical Devices

- Risk based classification
- Device classification depends on intended use and indications for use
- Devices are classified into 3 classes, based on the level of control needed to assure the safety and effectiveness of the device:
  - **Class I** (Low risk) – General controls
    - With exemptions
    - Without exemptions
  - **Class II** (Moderate risk) – General controls and special controls
    - With exemptions
    - Without exemptions
  - **Class III** (High risk) – General controls and premarket approval

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Premarket Requirements

- Classification determines type of premarket submission required for market clearance
- Class I and II devices typically require premarket notification (510k), unless exempt by regulation
- Class III devices require submission of premarket approval (PMA)

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USA

Premarket Requirements

Class I

- General controls sufficient to provide reasonable assurance of safety and effectiveness

- **General controls**:
  - ❑ Establishment registration
  - ❑ Medical device listing
  - ❑ Labelling requirements
  - ❑ Premarket notification (510k) submission

    (unless exempted by regulations)
  - ❑ Manufacture under GMP requirements

(Note: All classes are subject to general controls)

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Premarket Requirements

Class II

- General controls insufficient to provide reasonable assurance of safety and effectiveness. In addition to general controls, special controls are necessary

- **Special controls**:
  - ❑ Special labelling requirements
  - ❑ Mandatory performance standards
  - ❑ Post market surveillance

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Premarket requirements

Class III

- General controls and special controls insufficient to provide reasonable assurance of safety and effectiveness
- Premarket approval (PMA) is required : scientific review to ensure safety and effectiveness

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Premarket requirements

Premarket notification (510k)

- Premarket application to demonstrate that device is as safe and effective i.e. **substantially equivalent** to a legally marketed device (i.e. predicate device)
- A device is **substantially equivalent** to a **predicate device** if it
  - Has the same intended use and technological characteristics as the predicate device

    OR
  - Has the same intended use as the predicate device and different technological characteristics that do not raise new questions of safety and effectiveness

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USA

Premarket requirements

Premarket Approval (PMA)

- Scientific review to evaluate the safety and effectiveness of Class III devices.
- Sufficient valid scientific evidence to assure that the device is safe and effective for its intended use must be submitted
- An approved PMA is, in effect, a private license granting the applicant permission to market the device

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Premarket requirements

Premarket Approval (PMA)

Review of a PMA is a 4 step review process consisting of:

- Administrative and limited scientific review by FDA staff to determine completeness (filing review)
- In depth scientific and regulatory review by appropriate FDA scientific and compliance personnel (in depth review)
- Review and recommendation by the appropriate advisory committee (panel review)
- An FDA good manufacturing practices (GMP) inspection

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Quality System Requirements

- Quality system requirements are set out in the **Quality System Regulation**
- FDA does not require a manufacturer to register a quality system (a requirement of ISO and EN quality systems)
- FDA inspects quality system requirements in the course of regular inspections of a manufacturer's facilities
- Foreign manufacturers are also subject to FDA inspections

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Postmarket Requirements

- Requirements are set out in the Safe Medical Devices Act and FDA Modernisation Act:
- Manufacturers must submit medical device reports for device which caused death or serious injury, or, if the malfunction were to recur, would have cause death or serious injury
- User facilities must report device related deaths and serious injuries and submit a summary of all reports to FDA on an annual basis
- Manufacturers must have in place distribution records and other methods for tracking permanent implants or life sustaining/supporting devices used outside a facility
- Manufacturers and importers must report to FDA any removals and corrections of a device from the market

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Wide Range of Device Types – Different from Drugs

Orthopedic
General & Plastic Surgery
Cardiovascular
Radiology
General Hospital
Dental
Clinical Chemistry
Anesthesiology
Gastroenterology / Urology
Neurology
Microbiology
Physical Medicine
Ob / Gyn
Ophthalmic
Immunology
Hematology
Ear Nose & Throat
Toxicology
Pathology

GHTF* Definition of a Medical Device

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, *in vitro reagent or calibrator*, software, material or other similar or related article:-

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

· diagnosis, prevention, monitoring, treatment or alleviation of disease,
· diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
· investigation, replacement, modification, or support of the anatomy or of a physiological process,
· supporting or sustaining life,
· control of conception,
· disinfection of medical devices,
· providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

*Global Harmonization Task Force

GHTF Definition of a Medical Device

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, *in vitro reagent or calibrator*, software, material or other similar or related article:-

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.

The definition of a device for in-vitro examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an in-vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes.

Facts About MD & the Industry

- Wide range of device types
- Many different areas of clinical use
- Accessories (sometimes disposable) critical to device use
- Import of spare parts / expendables
- Globalization and global manufacturing sites
- Physician's influence on clinical outcome
- Risk sharing during device use

Globalized manufacturing sites

USA
Monitor B888
Monitor C124

Finland
Monitor AB12
Monitor B82

Mexico
Monitor V2B8

China
Accessories manufacturing

LNE

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 17230 rev 2

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 INFORMATION TECHNOLOGIES GmbH
Munzingerstrasse 5,
79111 FREIBURG GERMANY

pour les activités
for the activities

Conception et configuration d'équipements de cardiologie et de défibrillateurs
Conception de systèmes d'information d'imagerie

Design and configuration of cardiology equipment and defibrillators
Design of imaging information systems

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

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES GmbH
Munzingerstrasse 5 - 79111 FREIBURG - GERMANY

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* : **February 3rd, 2011 (included)**
Valable jusqu'au / *Expiry date* : **October 19th, 2012 (included)**
Etabli le / *Issued on* : **February 3rd, 2011**

For the General Director
Laurence DAGALLIER
Deputy Director

LNE N° 17230-2
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
Modifie le certificat 17230-1

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

ISO 13485 Certificate

- LNE certifies….
- *GE Medical Systems*
- *For the activities*
- Design and configuration of cardiology equipment…
- *Performed on the location of*
- *GE Medical Systems*
- *Complies with the requirements of the international standards*
- *ISO 9001:2008 – ISO 13485:2003*
- This certificate is issued according to the rules of G-Med certification
- G-Med *Notified Body for Medical Devices*

Conformity Assessment Bodies (CABs)

GHTF Definition of CABs

GHTF Definition of Conformity Assessment Body (CAB):

a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorised to undertake specified conformity assessment activities by a Regulatory Authority (RA) that will ensure performance of the CAB is monitored and if necessary withdraw designation

Conformity Assessment of QMS & Device

Conformity Assessment of Manufacturer's QMS

- Audits of the QMS
- Audits of the Post Market Surveillance process

Conformity Assessment of the Device Safety and Performance

- Review of device product technical documentation in dossier

✓Review of Declaration of Conformity

Accreditation of Conformity Assessment Bodies

For example: Assessment of Technical Competence

- Product knowledge
- Clinical experience
- Regulatory knowledge
- Auditing experience