



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

IEC PAS 63077 "Good Refurbishment Practice of Medical Imaging Equipment"

&

Regulations for refurbished medical devices in the USA, EU, Japan and ASEAN countries

Patricia Gehrlein

Vice Chair of the DITTA GRP working group

International Medical Device Conference (IMDC) 2019

15 October 2019

Kuala Lumpur, Malaysia



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Objectives of this presentation

By the end of this presentation you know more about

- DITTA & the Good Refurbishment Practice Working Group
- Refurbishment in the medical device industry
- Key aspects of IEC PAS 63077 “Good refurbishment practices for medical imaging equipment” related to the 5-step refurbishment process
- Regulations about refurbished medical devices in the USA, the EU, Japan and the ASEAN countries



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

DITTA is the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association

- DITTA is a non-profit trade association, created in 2000 and incorporated in 2012
- Our members are national and regional industry associations representing more than 600 medical technology manufacturers, responsible for designing and producing technologies and services such as
 - medical X-ray, computed tomography, ultrasound, nuclear imaging, radiation therapy and magnetic resonance imaging.



- DITTA has ten working groups including the **“Good Refurbishment Practice” (GRP) working group** which is focused on medical imaging devices.
- The companies being represented in the GRP working group are **original equipment manufacturers (OEMs)** who are best positioned to develop and implement refurbishment processes for their medical imaging devices.

SIEMENS
Healthineers

Canon
CANON MEDICAL SYSTEMS



PHILIPS



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

The refurbishment process in the medical device industry



Source: DITTA (2016): Good Refurbishment Practices for Medical Imaging Equipment. What customers should know.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Remanufacturing & Refurbishment in the medical device industry

- Outside the medical equipment industry the terms remanufacturing and refurbishment are often used as synonyms.
- Within the medical equipment industry we have to consider the term remanufacturer as defined by the U.S. Food and Drug Administration:
 - In the USA, the Food and Drug Administration defines ‘remanufacturer’ as “(...) any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.” (CFR 21 Part 820)
- This means that in the medical equipment industries there are differences between refurbishment and remanufacturing.
 - The most important aspect is: for refurbished medical (imaging) equipment there is **no significant change** of the **performance** or **safety specifications**, or in the **intended use** of the equipment compared to the specifications the manufacturer defined for the relevant new equipment.



IEC PAS 63077 & definition of refurbishment

IEC PAS 63077 “Good refurbishment practices for medical imaging equipment” describes and defines the process of refurbishment of used medical imaging devices to a condition of safety and effectiveness comparable to when new and without significantly changing the equipment’s performance, safety specification and/or intended use as in its original registration.

According to IEC PAS 63077 refurbishment is defined as follows:

3.10 REFURBISHMENT process or combination of processes applied during the expected service life to restore used medical imaging equipment to a condition of safety and effectiveness comparable to when new

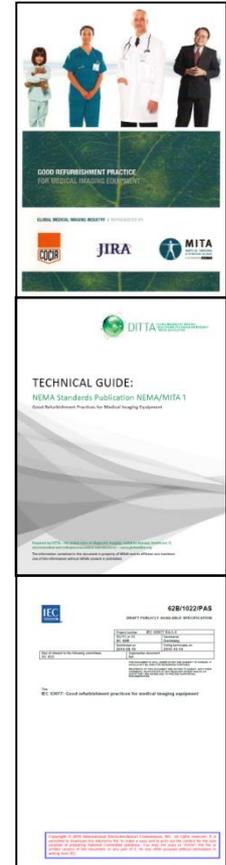
Note 1 to entry: Refurbishment can include activities such as repair, rework, replacement of worn parts, and update of software/hardware but shall not include activities that result in regulatory submissions.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

From “Good refurbishment practices” to IEC 63077

- The “**Good Refurbishment Practices**” (GRP) have been developed by DITTA and its member associations COCIR (EU), JIRA (Japan) and MITA (USA) filling a need in the global healthcare market for safe and effective refurbished medical equipment
- DITTA has triggered the idea to have an international standard on “Good Refurbishment Practices” and is further dedicated to promote the use and market access of refurbished medical imaging equipment as well as to emphasize on the importance to harmonize the refurbishment practices globally.
- With the support of DITTA, the US medical imaging and technology alliance MITA managed to develop and publish the **NEMA/MITA 1-2015** standard on “Good refurbishment practices for medical imaging equipment” in February 2016.
- DITTA (via MITA) collaborated with ANSI (American National Standards Institute) to file a request to the International Electrotechnical Commission (IEC) to publish the content of NEMA/MITA 1-2015 standard as an IEC PAS.
- In 2016, IEC published **IEC PAS 63077** on “Good refurbishment practices for medical imaging equipment” – content wise identical to NEMA/MITA 1-2015.
- In 2018 and 2019, IEC SC62B WG53 has been finalizing the standard by developing it from a Publicly Available Specification (PAS) to an international standard **IEC 63077**.





IEC PAS 63077 Content Overview

Foreword

1. Scope

2. Normative References

3. Terms and definitions

- 3.1 expected service life
- 3.2 intended use/intended purpose
- 3.3 manufacturer
- 3.4 medical imaging equipment
- 3.5 normal use
- 3.6 operator
- 3.7 refurbisher
- 3.8 patient
- 3.9 process
- 3.10 refurbishment
- 3.11 repair
- 3.12 rework
- 3.13 risk
- 3.14 used medical imaging equipment

4. General requirements for refurbishment of used medical devices

- 4.1 Quality management system
- 4.2 Resource management
- 4.3 Corrective and preventive action
- 4.4 Customer complaints
- 4.5 Production and service provision**
- 4.6 Control of non-conforming product
- 4.7 Post-market surveillance process
- 4.8 Document control
- 4.9 Purchasing**
- 4.10 Control of design and design changes

5. Specific requirements for good refurbishment practice

- 5.1 General
- 5.2 Selection of medical imaging equipment for refurbishment**
- 5.3 Evaluating market access requirements
- 5.4 Preparation for refurbishment, disassembly, packing, and shipment**
- 5.5 Planning**
- 5.6 Installation of safety updates (hardware/software)**
- 5.7 Performance and safety test**
- 5.8 Packing, shipment, and installation of refurbished medical imaging equipment**
- 5.9 Record of refurbishment
- 5.10 Refurbishment label



The refurbishment process

The refurbishment process consist of five essential steps:



Source: DITTA (2016): Good Refurbishment Practices for Medical Imaging Equipment. What customers should know.



The refurbishment process

Step 1: Selection



Every used medical imaging device, component and spare part is carefully selected and must fulfill high requirements regarding its:

- maintenance
- performance
- safety record

Only equipment that has met rigorous quality selection criteria becomes eligible for refurbishment.

According to IEC PAS 63077:

5.2. Selection of medical imaging equipment for refurbishment

The refurbisher shall determine the criteria that used medical imaging equipment must meet to qualify for refurbishment, based on an assessment of the risk (in accordance with ISO 14971:2007) associated with refurbishment, for any type of medical imaging equipment it wishes to process.

This determination shall consider the following items:

- a) intended use and normal use of the equipment;
- b) expected service life;
- c) applicable standards;
- d) service/maintenance history for the equipment;
- e) existing procedures for the refurbishment of medical imaging equipment, such as service, repair, production, and maintenance.

Used medical imaging equipment that is at the end of expected service life or that cannot be restored to at least the original safety and performance levels, including all mandatory safety updates, shall not be refurbished.



The refurbishment process

Step 2: De-installation

All systems and components are professionally de-installed by qualified personnel in a non-destructive manner and delivered safely back to the refurbisher.



According to IEC PAS 63077:

5.4 Preparation for refurbishment, disassembly, packing and shipment

The refurbisher shall have procedures in place to ensure that the medical imaging equipment has been suitably cleaned and disinfected to avoid harming any person involved in the disassembly, packing, and shipment. The medical imaging equipment shall be adequately disassembled (if necessary) and packed to prevent damage during shipment. Appropriate procedures shall be in place to avoid violation of privacy rules concerning patient data possibly stored on the relevant equipment.



The refurbishment process

Step 3: Refurbishment

All actions are performed in a manner consistent with product specifications and service procedures defined by the manufacturer. All steps in the process are performed by experts, trained using original manufacturer's specifications. Refurbishment is thorough and well documented. Performance and safety are tested.



According to IEC PAS 63077:

5.5 Planning

A REFURBISHMENT plan shall be developed and followed to restore the MEDICAL IMAGING EQUIPMENT to a condition of safety and effectiveness comparable to when new.

5.6 Installation of safety updates (hardware/software)

The REFURBISHER shall install all safety updates released by the MANUFACTURER for the relevant MEDICAL IMAGING EQUIPMENT since it was placed on the market.

5.7 Performance and safety test

Tests specified for the original MEDICAL IMAGING EQUIPMENT shall be conducted to verify that original performance and safety specifications are met, including all mandatory safety updates.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

The refurbishment process

Step 4: Installation

Product customization,
re-installation
and training are done
according to customer
needs.



According to IEC PAS 63077:

5.8 Packing, shipment, and installation of refurbished medical imaging equipment

Packing and shipment shall be adequate to prevent damage during transit and load/unload operations. Installation, inspection, and any required testing shall be performed according to documented procedures of the MANUFACTURER.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

The refurbishment process

Step 5: Warranty & After Sale Service

Just like with new equipment, service will be made available in the market where equipment is sold.



According to IEC PAS 63077:

4.5 Production and service provision

The REFURBISHER shall have documented procedures for REFURBISHMENT and service including but not limited to PROCESS validation, disinfection PROCESSES, identification, traceability and packaging. In addition, the organization shall make provisions to have the knowledge and the ability for installing and servicing MEDICAL IMAGING EQUIPMENT, or to ensure that servicing can be made available in those markets where the REFURBISHER makes refurbished MEDICAL IMAGING EQUIPMENT available on the market.

4.9 Purchasing

The organization shall document procedures to ensure that purchased components, service parts and other materials such as packaging material, services as needed for REFURBISHMENT conforms to purchasing information as specified by the manufacturer of the medical imaging equipment. The REFURBISHER shall establish dedicated supplier management capabilities when components, services, or other materials such as packaging materials, services are purchased.



Refurbished devices according to IEC PAS 63077 in comparison to new devices and 2nd hand devices

	New Medical Imaging Devices	Refurbished Medical Imaging Devices according to IEC 63077 PAS	2nd hand Medical Imaging Devices refurbished by non-OEMs or sold non-refurbished by dealers
<i>OEM test instructions</i>	✓	✓	Typically no
<i>Declaration of Conformity (DoC)</i>	issued	confirmed ¹⁾	Typically no
<i>CE - mark (e.g. in EU)</i>	issued	confirmed ²⁾	Typically no
<i>Post-market surveillance</i>	✓	✓ ³⁾	Typically no
<i>QMS ISO 13485</i>	✓	✓ ⁴⁾	Typically no
<i>Performance and safety test</i>	✓	✓ ⁵⁾	Typically no

1) 4.6. & 4.10 IEC PAS 63077 / 2) This means that the manufacturer declares that the product meets all legal, regulatory, and technical requirements for CE marking / 3) 4.7. IEC PAS 63077 / 4) 4.1 IEC PAS 63077 / 5) 5.7 IEC PAS 63077

Warranty time, spare part availability, and service contracts depend on the offers by the OEMs.



Price advantage, access, affordability and quality of healthcare

- **Cost savings and increased access to affordable and high quality healthcare**

- Refurbished medical imaging devices and spare parts can be offered at a lower price than the comparable new ones.
- Cost savings can range between 10% to 50% in comparison to a new medical imaging device, depending on the product and its configurability.
- Hospitals and medical centers with budget restrictions are enabled to purchase high-quality devices and can make a positive contribution to increased access to affordable and high-quality healthcare.



- **Improving the overall quality of healthcare**

- The replacement of used and outdated medical devices with medical imaging devices refurbished according to IEC PAS 63077 may result in improved outcomes for patients in the areas of diagnosis and therapy.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Summary & Main Take Away's: Medical imaging devices refurbished according to IEC PAS 63077

- **QUALITY:** Refurbishment according to IEC PAS 63077 allows to have a refurbished medical imaging device in condition of safety and effectiveness comparable to when new and without significantly changing the equipment's performance, safety specification and/or intended use as in its original registration.
- **SAFETY:** Those medical imaging devices that are refurbished by the OEMs will receive all safety-relevant updates and can also be provided with the latest software versions.
- **WARRANTY & AFTER SALE SERVICE:** The DITTA member companies offer refurbished medical imaging devices with warranty, spare part availability and after sale service. The exact conditions vary depending on the individual offers.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

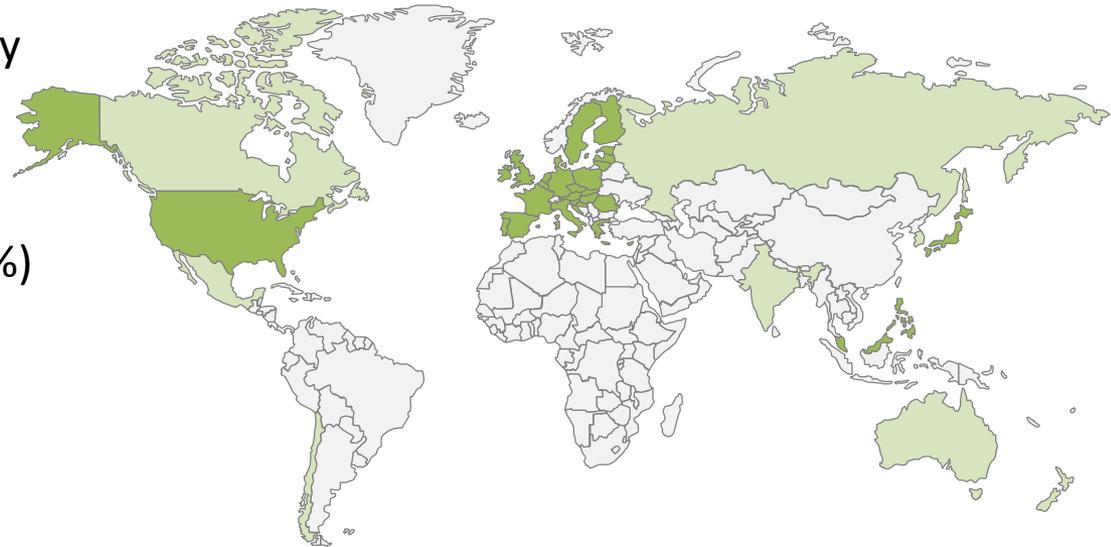
Regulations for Refurbished Medical Devices in the USA, EU, Japan and ASEAN countries



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

The market for refurbished medical imaging devices: US, EU, Japan, ASEAN

- Refurbishment of medical imaging devices accounted for **global revenue** of approximately 865 million Euros in 2017.
- Approximately 70% of all refurbished medical imaging devices are sold in the **U.S.** (46%) and the **European Union** (24%).
- In Asia the biggest markets for refurbished medical imaging devices are in **Japan** and **South Korea**.
- In ASEAN refurbished medical imaging devices are sold to **Singapore, Malaysia** and the **Philippines**.





- In the United States, refurbished medical devices are permitted to be sold and placed on the market. As a general rule, a refurbished medical device, just as a new medical device, must possess a relevant premarket clearance or authorization in order to be placed on the market (e.g., 510(k) premarket notification for Class II or a Pre-Market Approval (PMA) for Class III).
- Refurbished medical devices are also allowed to be imported into the United States, provided that the source site is registered with the FDA as "Foreign Exporter."
 - The FDA does not define the term refurbishment and refurbishment is deemed a servicing activity.





European Union



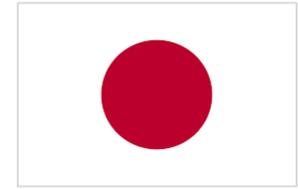
- To import and sell medical devices - new and refurbished - need to comply to the EU laws and regulations that are applicable at the time they are placed onto the EU market.
- Medical devices - both new and refurbished are regulated by the EU Medical Device Directive (MDD) (93/42/ECC). Starting from May 2020, the EU Medical Device Regulation (MDR) 2017/745 will be applicable for new and refurbished medical devices.
- Neither the Medical Device Directive (MDD), nor the Medical Device Regulation (MDR), define 'refurbishment'.



- The MDR definition of 'fully refurbishing' is similar to the term "remanufacturing" used in the United States. It refers to the complete rebuilding of a device or the making of a new device from used devices. This is not identical to the definition of 'refurbishment' provided in IEC PAS 63077.
- There are no country specific regulations for refurbished medical devices.



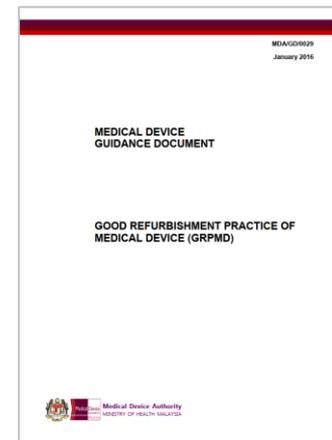
Japan



- In Japan, the regulations do not include a specific definition regarding refurbishment. Refurbished medical devices are regarded as a sub-set of used medical devices.
- The import of refurbished medical devices (including their spare parts) is permitted into Japan. The conditions that need to be met are : 1) refurbishment is performed in the facilities which meet JGMP-QMS requirements and 2) the equipment should be shipped from original manufacturer of the original product.
- New medical devices, used medical devices and the repair of medical devices are all regulated categories. The same requirements for new products are applied to used medical devices (i.e. compliance to JIS T0601-1:2017).



- The import of refurbished medical imaging devices is permitted with a valid registration certificate. There is a specific policy in place relating to the control of activities on refurbishment of medical devices. It has been outlined in the “Circular Letter of the Medical Device Authority No. 1 Year 2016”.
- The Medical Device Guidance Document “Good Refurbishment Practice of Medical Device” describes the process by which the industry refurbishes medical devices.
- Refurbished medical devices require a similar type of registration dossier as a new medical device submission. The refurbisher must also be able to demonstrate that they have followed the GRP process specified by Malaysia Medical Device Authority.





Singapore, Philippines, South Korea

- **Singapore:** There are no specific regulations on refurbishment. Import of refurbished medical imaging devices can only take place if the product is registered by Health Science Authority. There are no special requirements or restrictions regarding the import of refurbished medical imaging devices.
- **South Korea:** Every refurbished medical imaging device imported to South Korea shall be tested by Medical Device Importer or Medical Device Manufacturer of the refurbished medical imaging device. If the Medical Device Importer or Medical Device Manufacturer cannot test the refurbished system, a 3rd party test lab may test.
- **Philippines:** There is no specific regulation that targets refurbished medical imaging devices. However, Import Clearance must be obtained by fulfilling the requirements written in Bureau Order No. 020 s. 2007. In addition, a custom release clearance for all radiation emitting devices is needed.





Vietnam, Thailand, Indonesia

- **Vietnam:** Import of refurbished medical devices and spare parts is banned according to Government Decree 69/2018/ND-CP (15 May 2018) and Circular 12/2018/TT-BYT (15 June 2016).
- **Thailand:** Import of refurbished medical devices and spare parts is not permitted in practice.
- **Indonesia:** It is not permitted to import refurbished medical devices or spare parts.





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Main take aways: Regulations for refurbished medical devices

- Refurbished medical imaging devices are accepted in major markets around the world, such as USA, EU and Japan.
- The refurbished medical devices imported to and distributed in these countries are approved with the relevant documents and labels by the respective local authorities.
- There are import bans for refurbished medical devices in three ASEAN countries (Vietnam, Thailand, Indonesia).
- Malaysia's regulations use the "Good Refurbishment Practice" as the way to regulate the import and sale of refurbished medical devices.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Final Summary & main take aways

- DITTA promotes the use of and market access for refurbished medical imaging equipment according to IEC PAS 63077 and emphasizes on the importance to harmonize the refurbishment practices globally.
- DITTA does not want refurbished medical equipment which is refurbished to IEC PAS 63077 to be considered used medical equipment.
- DITTA wants governments to distinguish between used medical equipment and refurbished medical equipment.
- DITTA wants refurbished medical imaging equipment refurbished according to IEC PAS 63077 allowed to be imported and distributed for diagnostic and treatment purposes.



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

IEC PAS 63077 "Good Refurbishment Practice of Medical Imaging Equipment" &

Regulations for refurbished medical devices in the USA, EU, Japan and ASEAN countries

*International Medical Device Conference
(IMDC) 2019*

15 October 2019

Kuala Lumpur, Malaysia

Contact Details

Patricia Gehrlein

- **Vice Chair of the DITTA Working Group „Good Refurbishment Practices“**
- **Senior Policy Advisor for Refurbished Systems, Government Affairs & Policy, Siemens Healthineers**
- **E-Mail:**
patricia.gehrlein@siemens-healthineers.com



JIRA

MEDEC



IMEDA



**ITAC
health**



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

Annex



IEC PAS 63077

According to IEC PAS 63077:

4.1 Quality management system

REFURBISHMENT of USED MEDICAL IMAGING EQUIPMENT shall be conducted under a quality management system (QMS) of the REFURBISHER in compliance with ISO 13485:2016. In addition to ISO 13485:2016, the provisions in paragraphs 4.2 to 4.11 shall be applied.

According to IEC PAS 63077:

4.7 Post-market surveillance process

The REFURBISHER shall collect feedback from customers and establish documented procedures to notify regulatory authorities of adverse events. The PROCESS shall also determine if the adverse event is related to the REFURBISHMENT of the USED MEDICAL IMAGING EQUIPMENT or needs to be reported to the original MANUFACTURER.

The REFURBISHER shall also establish his or her own post-market surveillance PROCESS to monitor whether the additional RISKS resulting from REFURBISHMENT have been adequately mitigated.

The REFURBISHER shall enable monitoring of its installed base of refurbished MEDICAL IMAGING EQUIPMENT to allow for update management for safety and effectiveness.

According to IEC PAS 63077:

4.5 Production and service provision

The REFURBISHER shall have documented procedures for REFURBISHMENT and service including but not limited to PROCESS validation, disinfection PROCESSES, identification, traceability and packaging. In addition, the organization shall make provisions to have the knowledge and the ability for installing and servicing MEDICAL IMAGING EQUIPMENT, or to ensure that servicing can be made available in those markets where the REFURBISHER makes refurbished MEDICAL IMAGING EQUIPMENT available on the market.

According to IEC PAS 63077:

4.9 Purchasing

The organization shall document procedures to ensure that purchased components, service parts and other materials such as packaging material, services as needed for REFURBISHMENT conforms to purchasing information as specified by the manufacturer of the medical imaging equipment. The REFURBISHER shall establish dedicated supplier management capabilities when components, services, or other materials such as packaging materials, services are purchased.



Remanufactured goods are included into the EU-Vietnam FTA

ARTICLE 3: DEFINITIONS

A **remanufactured good** means a good in HS chapters 84, 85, 87, 90 and 9402, except Annex [Z] that:

- a) is entirely or partially comprised of parts obtained from goods that have been used beforehand; and
- b) has similar performance and working conditions as well as life expectancy compared to the original new good and is given the same warranty as the new good.

ARTICLE 5: REMANUFACTURED GOODS

The Parties shall accord to remanufactured goods the same treatment as that provided to new like goods. A Party may require specific labelling of remanufactured goods in order to prevent deception of consumers. The application of this Article is subject to a transitional period of no longer than three years from the entry into force of this Agreement.



DITTA welcomes that the EU-Vietnam FTA considers the equal treatment of remanufactured goods and would support a practical implementation in the context of refurbished medical imaging devices.