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Guideline For Registration Of Used And Refurbished Medical Equipment

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Guideline For Registration of Used and Refurbished Medical Equipment

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ACKNOWLEDGMENT

In the development of this guidance document, the following resources and bodies were referenced:

a. The Common Submission Dossier Template (CSDT) of the Asian Harmonization Working Party (AHWP).
b. Medical Device Regulations of the Malaysia, Canada, and Australia
c. Principles of Medical Device Classification: GHTF/SG1/N77:2012
d. The European Standards (Medical Devices)
e. MDA (Malaysia Medical Device Authority) Good Refurbishment Practice of Medical Device (GPRMD)
f. Principles of Conformity Assessment of Medical Devices: GHTF/SG1/N78:2012
g. The Medical Devices Regulations – Global overview and guiding principles of WHO
h. The FDA's Technical Advisory Committee on Medical Devices (TAC-MD)
i. Traditional Medicine Practice Council (TMPC)
j. Nuclear Regulatory Authority (NRA)
k. Health Facilities Regulatory Agency (HeFRA)
l. Christian Health Association of Ghana (CHAG)
m. Ministry of Health (MOH)
n. Ghana Health Service (GHS)
o. Komfo Anokye Teaching Hospital
p. Korle-Bu Teaching Hospital
q. Tamale Teaching Hospital
r. Ho Teaching Hospital
s. Cape Coast Teaching Hospital

EXECUTIVE SUMMARY

The guideline aims to provide stakeholders with the regulatory framework for refurbished and used medical equipment in Ghana. The refurbished and used medical equipment market provides an avenue for cheaper access to healthcare delivery and reduces cost in developing countries where these equipment are donated or purchased for use.

The relevant stakeholders include parts/components suppliers, original equipment manufacturers (OEM), industry associations, standard bodies, service providers, importer, distributors, and marketers.

The high cost of new medical equipment makes it almost impossible for healthcare facilities to procure highly sensitive medical equipment for diagnostics and quality healthcare delivery. As a result, healthcare facilities in developing countries rely on refurbished or used medical equipment for the diagnosis and treatment of patients.

To achieve their desired role in healthcare delivery, refurbished and used medical equipment must be safe, of good quality and perform as intended by the Manufacturer. It is expected that refurbished or used medical equipment are handled only by professionals who have the required competence in the operation and performance of the medical equipment.

Regulatory oversight is, therefore, crucial to ensure compliance to the safety, quality, and performance standards of refurbished and used medical equipment.

1.0. INTRODUCTION

Medical equipment constitute essential components in the delivery of quality health care. Thus, in a regulatory framework, the safety, quality, and performance of medical equipment are important. Experts have estimated that new versions of medical equipment are introduced to the market periodically between 18 to 24 months following which they are disposed or sold as used or refurbished within or after the life cycle of the medical equipment.

To ensure the safety, quality, and optimum performance of refurbished or used medical equipment, regulatory oversight is important because most of these medical equipment are sold for use or donated to recipients in developing countries.

In pursuance of Section 148 of the Public Health Act, 2012, Act 851, this Guideline is hereby promulgated for information, guidance, and strict compliance by all stakeholders on the procedure and requirements for the registration of refurbished or used medical equipment in Ghana.

This guideline must be read and used in conjunction with the enabling legislation, the Public Health Act, 2012, Act 851, Part 7, the current version of the Guideline for the Registration of Medical Device, the Guideline for Donation of Medical Devices, the Guideline for the Importation of Medical Devices and other relevant Guidelines and Regulations issued by the Food and Drugs Authority.

1.1. LEGAL BASIS

The core mandate of the FDA to maintain Public Health and Safety is enshrined in the Public Health Act, 2012 (Act 851), Sections 118, 122, 123 and 148 as follows.

Section 118 (1) 'A person shall not manufacture, prepare, import, export, distribute, sell, supply or exhibit for sale a food, drugs, herbal medicines, cosmetics, **medical devices** or household chemical substances unless the article has been registered by the Authority'

Section 122 (1) 'A person who has not been issued with a license or permit under this Part, shall not import a food, drugs, herbal medicines, cosmetics, **medical devices,** or household chemical substances'

Section 123 (1) 'A person shall not manufacture, import, export, supply, possess or offer for sale a counterfeit food, drugs, herbal medicines, cosmetics, **medical devices,** or household chemical substances'

Section 148 (1) The Authority may issue guidelines and codes of practice in connection with food and drugs and any other products or **devices** regulated by the Authority to persons in the food and drugs industry and the persons shall comply with the guidelines and codes of practice

Section 148 (2) (c) 'Without limiting subsection (1) the Authority may issue guidelines for the regulation of importation or exportation of food, drugs, herbal medicines, cosmetics, **medical devices,** or household chemical substances in order to ensure compliance with this Part.

1.2. SCOPE

This guideline specifies the requirements for the registration of refurbished and used medical equipment intended for distribution in Ghana. **Single-use, implantable, and disposable medical devices are excluded under this guideline.**

In instances where the refurbished or used medical equipment to be imported is a donated item, reference should be made to the Guideline for Donation of Medical Devices.

2.0. DEFINITIONS AND ACRONYMS

AHWP: Asian Harmonization Working Party
CSDT**:** Common Submission Dossier Template
DCEO: *Deputy Chief Executive Officer*
DoC: Declaration of Conformity
FDA: Food and Drugs Authority
GPRMD: Good Refurbishment Practice of Medical Device
GSA**:** Ghana Standards Authority
IEC: International Electrotechnical Commission
ISO: International Standards Organization

MDA: Malaysia Medical Device Authority

MDCHC: *Medical Devices, Cosmetics and Household Chemicals*

ME: Medical Equipment

MEHR: Medical Equipment History Record

OEM: Original Equipment Manufacturer

SUD**:** Single Use Devices

In these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

Applicant: The product owner or license holder. Representatives of license holders may not hold themselves as applicants unless they own the product.

Authorized Local Representative (local agent): A local representative or company which is incorporated in Ghana and listed by FDA to import medical equipment on behalf of a non resident applicant.

Authority: The Food and Drugs Authority, Ghana.

Refurbished Medical Equipment: Refers to medical equipment which has been completely rebuilt/made as new from used equipment and is assigned a new 'useful life'. It would also be considered as a new equipment if a new intended purpose was assigned.

Maintenance: Maintenance consists of schedule maintenance and unscheduled maintenance. Scheduled maintenance is planned maintenance program to ensure an optimum performance, safe operation, minimum downtime, and maximum useful life from each medical device. Unscheduled maintenance involves those actions necessary to restore normal function, safety, performance, and reliability to malfunctioning medical devices.

Medical Device or Device: Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, *in-vitro* reagent, or other similar or related article, including any component, part, or accessory, which is:

(a) Recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them.

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals or.

(c) Intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Medical Equipment: Refer to medical devices requiring calibration, maintenance, repair, user training and decommissioning-activities usually managed by clinical engineers. They are used for the specific purpose of diagnosis and treatment of disease or rehabilitation following disease or injury; they can be used either alone or in combination with any accessory, consumable or other piece of medical equipment.

Medical Equipment Manufacturing: Includes all operations involved in the production, preparation, processing, filling, refining, transformation, packing, packaging, re-packaging, and labelling of medical equipment.

Medical Equipment Manufacturer: A person or party responsible for designing, manufacturing, packaging, and labelling medical equipment before placing it on the market; also responsible for providing documentation, instructions and recommendations for the installation, use and maintenance of the equipment to ensure its performance, as well as the safety of patients and health workers.

Refurbishing: a systematic restoration that ensures safety and effectiveness of the medical equipment without significantly changing the equipment's safety, quality, performance, and/or changing intended use or its original specification. The restoration includes actions such as repair, rework, software/hardware updates, and the replacement of worn-out parts with new parts.

Refurbisher: a person/company that restores an equipment to a condition of safety and effectiveness that is comparable to a new medical equipment. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the equipment, and replacement of worn-out parts.

Single-Use Medical Device: Also referred to as a "disposable device", intended to be used on one patient during a single procedure. It is not intended to be reprocessed/refurbished (cleaned, disinfected, or sterilized) or used on another patient.

Used/Second hand Medical Equipment: medical equipment which are already on the market and have been 'pre-owned' and used, and subsequently 'sold on' for the same continued use.

Validation: Confirmation by examination and provision of objective evidence that a particular requirement for a specific intended use can be consistently fulfilled

Vendor: a person or company offering a medical equipment for sale

3.0. GENERAL REQUIREMENTS

3.1. Principles of Good Refurbishment Practice

Good Refurbishment Practice (GRP) comprises a set of standard operating procedures and dedicated quality requirements that ensure a refurbished medical equipment is as safe and effective as when it was new. Any upgrade processed during refurbishment under GRP shall be performed in a manner consistent with the original product specifications and service procedures defined by the manufacturer for that medical equipment.

Medical Equipment intended as not eligible for refurbishment and does not meet, or cannot be refurbished to meet the manufacturer's initial specification shall, therefore, not be refurbished.

Good Refurbishment Practice for Medical Device (GRPMD) helps to fulfil regulatory requirements for safe and effective refurbished medical devices.

3.2. General Quality

The applicant shall ensure that the used and refurbished medical equipment is fully operational as per the verification standards and/or Manufacturer's specification, and that all essential accessories and supplies are available.

3.3. Documentation

A checklist completed by the applicant to ensure that all parts, components, accessories, supplies (for initial operations) etc. are included. Checklists are often found in operation, service and/or maintenance manuals produced by the manufacturer or refurbisher.

Operating and service manuals with part lists are critical to the usability of the used or refurbished medical equipment and should accompany the medical equipment in question.

3.4. Safety, Specifications and Standards

Refurbished or used medical equipment should meet or exceed existing safety and performance specifications provided by the manufacturer, and where applicable, standards promulgated by international bodies such as International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and standards approved by Ghana Standards Authority (GSA).

Medical equipment that has not been approved by the appropriate regulatory agency in the country of origin shall not be accepted for registration.

Medical equipment that is the subject of manufacturer recalls or hazard alerts shall be updated to the new requirements or shall not be accepted.

When the refurbished medical equipment is to be placed on the market, the refurbisher shall ensure that the testing, commissioning, and maintenance of the refurbished medical equipment complies with the manufacturers' instruction as per the original device.

3.5. Registration

Per section 118 of the Public Health Act, 2012 (Act 851) medical devices including used and refurbished medical equipment shall be duly registered with the FDA. The importer shall be required to monitor the quality, safety and performance of the medical equipment and update the FDA with the performance of the equipment.

3.6. Fees

All fees are specified in the current FDA Fee Schedule.

3.7. Sampling

Sampling of the refurbished or used medical equipment shall be in conformity with the FDA sample schedule. On-site verification and validation will also be carried out where applicable.

3.8. Letter

All applications for registration of refurbished or used medical equipment shall be made by submitting a letter addressed to:

The Chief Executive Officer,
Food and Drugs Authority
P. O. Box CT 2783
Cantonments, Accra

3.9. Applicant

An application for processing of medical equipment can be made by a manufacturer, a refurbisher, or by an importer of the medical equipment. The personnel submitting this application would be responsible for the product and all issues relating to the medical equipment, including any information accompanying the medical equipment.

A non-resident applicant importing such medical equipment would be required to appoint a local agent with the requisite mandate to represent the said applicant. The agent would be required to produce the relevant documentation, or any other documentation, affirming his/her appointment as an agent for the equipment.

3.10. Local Agent

A local agent resident in Ghana or a corporate body registered in Ghana, with the relevant mandate, is required to act on the non-resident applicant's behalf as regards matters relating to the registration of a medical equipment in Ghana. The Local Agent would, among other things:

Monitor the equipment and appropriately inform the Authority of any relevant issues relating to the equipment, including any serious manufacturing defects with the potential to endanger the safety and/or health of the patient, operator or any other person, or public health.

Facilitate communication between the non-resident applicant and the Authority on matters relating to the equipment.

Handle equipment recalls.

Provide technical support and services to users of the equipment.

3.11. Labelling

Refurbishers of medical equipment are required to indicate that the medical equipment is a refurbished medical equipment. The refurbishment date shall also be indicated. Other labelling requirements are as prescribed by the FDA's labelling requirements.

4.0. SPECIFIC REQUIREMENTS

4.1. Refurbished Medical Equipment

Refurbishers of medical equipment are responsible for restoring equipment to its original working condition and are therefore subject to general principles of liability. Refurbishers are required to follow the Good Refurbishment Practice (GRP) established for manufacturers of medical equipment.

Such equipment are expected to be restored to the manufacturer's specifications.

4.2. Requirements for Refurbished Medical Equipment

- Declare the original manufacturing date including information on multiple previous users.
- Document the source of all purchased equipment.
- Label the equipment with the refurbishers name and indicate that the equipment has been refurbished.
- Verify and document the operation of the equipment and the performance standards used to calibrate it (i.e., Operational/User manual).

Submit and include the following:

- The requisite certificate of analysis (i.e., performance and safety tests).
- Good Refurbishment Practice (GRP) certificate of the refurbisher.
- Refurbishment Report and certificate
- Refurbisher's manufacturing licence and a Certificate of Free Sale.
- Refurbishment plan/protocol
- Documentation on the installation of performance update (if applicable)
- GRP Declaration (release)
- Declaration on the original manufacturer and user(s)

4.3. Used Medical Equipment

Medical equipment which are already on the market having been 'pre-owned' and used, and subsequently 'sold on' for the same continued use must be fully operational and meet standard requirements for performance.

Adequate local arrangements for the necessary training, maintenance, spare parts, and user's and service manuals must be readily available for such equipment.

4.4. Requirements for Used Equipment

- Document the source of all purchased equipment.

- Document components that were replaced and the repair services that were performed on the equipment. (i.e., Maintenance and service history of the medical equipment).

Submit and include the following:

- User Manual
- Service and/or Maintenance Records and Manual
- Installation manual
- Training Manual
- Guaranteed source of spare parts
- Guaranteed source of consumables
- Accessories
- Decommissioning report
- Maintain a customer complaint file and document the actions that were taken to resolve customer complaints.

Damaged medical equipment which are imported purposely for repairs locally for use will not be permitted. Appropriate sanctions per clause 6.0 will apply where necessary.

4.5. On-site Verification and Validation

The precision and accuracy of refurbished equipment are of utmost importance for the health and safety of patients. The effective use of used and refurbished medical equipment prevents dire consequences for patients. Optimum operating conditions are difficult to control in clinical settings and can affect the performance of clinical equipment. Verification and validation are, therefore, necessary to determine an equipment's optimum operating conditions, safety, and efficiency.

The following documents are required for on-site verification and validation:

- Operational Manual
- Maintenance and/or service manual
- Installation Qualification report
- Performance Qualification report
- Operational Qualification report
- Calibration Procedure (where applicable)
- Calibration Records (where applicable)
- Standards for Calibration (where applicable)
- Refurbishment Report
- Maintenance record where applicable

4.6. Radiation Emitting (Radiological) Equipment

Due to the harmful effects associated with the use of radiation emitting medical equipment, the Nuclear Regulatory Authority (NRA) Act, 2015 (Act 895) mandates the NRA to ensure the protection and safety of humans and the environment from exposure to radiations from these equipment.

In order to ensure efficient regulation of radiological refurbished equipment in compliance with the Public Health Act, 2012 (Act 851) and the NRA Act, 2015 (Act 895), the FDA collaborates with the Nuclear Regulatory Authority, the National Authority mandated to certify the setting up and operation of diagnostic radiology facilities in Ghana.

As part of the requirements for the registration of refurbished radiological equipment, an Authorization Certificate for possession and use from the NRA is thus, required to be submitted to the FDA to demonstrate compliance of the equipment to the NRA Act, 2015 (Act 895) and the Public Health Act, 2012 (Act 851).

4.7. Decommissioning and disposal of Refurbished and Used Medical Equipment

A detailed plan for decommissioning and disposal of medical equipment shall be provided to the FDA and the exercise shall be carried out in compliance with the relevant laws as follows:

a) Disposal of equipment contaminated with biological, chemical, or other hazardous materials must comply with environmental laws that govern the discharge of contaminants into the natural environment.

b) Disposal of equipment associated with workplace hazards must comply with occupational health and safety laws that govern workplace safety.

c) Disposal of equipment with stored patients' personal health information must comply with health privacy and data protection laws.

d) Disposal of equipment associated with radioactive components (i.e., medical equipment and/or sources) shall comply with the unique legislative regime(s) governing such equipment.

5.0. TIMELINES

All applications for registration of used and refurbished medical equipment shall be processed within a period of six months, unless the application qualifies for expedited review as outlined in the Guideline for the Registration of Medical Devices.

6.0. SANCTIONS

A person who contravenes these Guidelines or sections thereof is liable to regulatory sanctions per Sections 119 and 132, Part 7, Act 851, the Public Health Act, 2012 which shall be imposed by the Authority. These sanctions may include, but not limited to, any of the following:

6.1 Suspension of the processing of a pending application for donation.

6.2 Suspension of the processing of a pending import license application.

6.3 Cancelation of an import license

6.4 Payment of administrative charges as per the current Fees and Charges (Amendment) Instrument.

7.0. PENALTIES

In line with the provisions of Section 129, Part 7, Act 851, the Public Health Act, 2012, a person who contravenes these Guidelines commits an offence and is liable on summary conviction to a fine of:

7.1 not less than seven thousand five hundred (7,500) penalty units and not more than fifteen thousand penalty units (15,000), or

7.2 to a term of imprisonment of not less than fifteen years and not more than twenty-five years, or

7.3 to both.

7.4 in case of a subsequent offence, to a fine of not less than five hundred (500) penalty units or to a term of imprisonment of not more than two years or both.

ANNEX I

1.0 REFURBISHMENT PROCESS

Each step of refurbishment process incorporates dedicated activities and necessary resources. These resources include qualified people, tools, instructions, files/records/documents, test equipment, parts, packing material, etc.

As with the manufacturing process of a new medical device, the refurbishing process shall meet critical specifications (e.g., environmental conditions such as facility temperature and humidity) as defined by the original manufacturer.

1.1. Selection of medical equipment for refurbishment

The selection of medical equipment to be refurbished, is based on the principle that when completed, it will have the same quality, performance, safety and intended use comparable to the manufacturer's original specification.

The following criteria are considered important when considering the refurbishment of used medical equipment:

a) Type, configuration and condition of the used medical equipment, age, upgradeability, and the phase in the life cycle of the medical equipment.

b) The phase in the life cycle of the medical equipment is generally defined by the availability of spare parts. The lack of spare parts will limit a refurbished medical equipment's serviceability. Table 1 in the Annex indicates examples of activities, information and resources needed on selection of medical equipment for refurbishment.

Table 1. Activities, information, and resources needed on selection of medical equipment for refurbishment

ACTIVITY	INFORMATION AND RESOURCES REQUIRED (*Examples*)
Evaluate type, age, and configuration of the medical equipment	Product service history, data of the Installed Medical equipment Database
Evaluating the condition of a medical equipment	Service records of the relevant equipment; site and incoming check instructions; service instructions by the manufacturer. Equipment condition requirements that have to meet the refurbishment criteria
Evaluating upgradeability of software and hardware status	Device upgradeability documentation of the equipment manufacturer/availability of software update
Evaluating availability of spare parts and service	Spare parts and service availability

1.2. Dismantling/Disassembly, Packaging and Transportation

1.2.1. Dismantling/disassembly

a) Dismantling/disassembly of medical equipment shall be done in accordance with manufacturer instructions and by trained, certified and competent technical professional.

b) Where a piece of medical equipment has been used in a special environment (e.g. emergency room, operating room) it might be necessary to first perform a decontamination/disinfection process at the place of disassembly, to limit the risk of exposure to pathogens. Table 2 indicates examples of activities, information and resources needed in dismantling, packaging, and transportation.

Table 2. Activities, information, and resources needed in dismantling, packaging and transportation

ACTIVITY	INFORMATION AND RESOURCES REQUIRED (*Examples*)
Medical equipment checks at customer's Site	Instructions of the manufacturer for medical equipment check and the tools needed as specified by the equipment manufacturer.
Preliminary Decontamination / disinfection	Preliminary decontamination instructions.
Professional disassembly	Manufacturer instructions for medical equipment disassembly, appropriate tools needed for medical equipment disassembly as specified by the original manufacturer, appropriate tools for transportation lock, trained personnel Performing the disassembly.

1.2.2 Packaging and transportation (Before Refurbishment)

The refurbisher is responsible for developing instructions to make sure that medical equipment to be refurbished are not damaged during packaging and transportation. The purpose of this process is to ensure that any medical equipment that is destined for refurbishment will be packed and transported in such a manner that prevents damage during transportation. All instructions shall be validated. Table 3 indicates examples of activities, information and resources needed on packaging and transportation.

Table 3. Activities, information, and resources needed on packaging and transportation

ACTIVITY	INFORMATION AND RESOURCES REQUIRED (EXAMPLES)
Packaging of the used medical equipment	Manufacturer product instructions for packaging, including specified tools, packing material e.g., frames, etc.
Transportation to the refurbishment Facility	Manufacturer product instructions for transportation, including specified tools for monitoring transportation e.g., shock indicators.
Incoming inspection	Validated incoming inspection instructions, specified tools.

1.3. Refurbishment

1.3.1 Refurbishment planning

a. This process depends on the medical equipment to be refurbished. The medical equipment configuration shall be defined either by the refurbisher or according to customer requirements. The final configuration of the refurbished medical equipment shall be within the scope of the manufacturer's specification.

b. The refurbishment planning process is a critical phase for refurbishment because all necessary actions shall be thoroughly assessed and determined. Throughout the refurbishing process, the Medical Equipment History Record (MEHR) shall be continuously updated.

c. The refurbisher planning the necessary refurbishment actions shall be competent to ensure that the required actions do not represent a modification that might impair the original identity and approved configuration of the medical equipment which can pose a potential risk. Due to the critical nature of the refurbishment process, the refurbisher shall have reliable controls and have it defined in detail in the quality management system of the medical equipment.

d. A refurbished medical equipment that does not have the same intended use and specification after restoration shall be treated as a new medical equipment. The refurbishment of medical equipment shall not compromise on safety, quality and

performance. Table 5 indicates examples of activities, information and resources needed on refurbishment planning.

Table 4. Activities, information and resources needed on refurbishment planning

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Check for relevant technical documentation for detailed planning to ensure that the medical equipment will be refurbished according to original manufacturer product specifications.	▪ Original manufacturer product specifications. ▪ Technical documentation for the planning of refurbishment.
Check for necessary field updates Regarding safety, reliability, performance etc.	Original manufacturer product specifications.
Planning appropriate updates	The results of product surveillance of the relevant medical equipment.
Planning cosmetic, mechanical and electrical refurbishment as well as medical equipment configuration.	Original manufacturer product specifications and documentation, e.g. medical equipment configuration documentation.
Planning of medical equipment testing.	Original manufacturer product specifications and documentation.
Preparation of GRP declaration.	Technical documentation for the respective medical equipment.
Planning of packaging & transportation	Original manufacturer product specifications and documentation.
Planning of reinstallation and start-up check at the customer's site.	Original manufacturer product specifications and documentation.

1.3.2. Decontamination and sterilisation

a. The refurbisher shall establish, document, and maintain requirements for decontamination of refurbished products, which may include cleaning, disinfection, and sterilisation where applicable.

b. A used medical equipment can become contaminated when used in a clinical environment. The purpose of this process is to make sure that any medical equipment that is to be refurbished will bear no risks of infection to any person during or after the refurbishment process. Table 4 indicates examples of activities, information and resources needed on decontamination and sterilisation.

Table 5. Activities, information, and resources needed on decontamination and sterilization

ACTIVITY	**INFORMATION AND RESOURCES REQUIRED** (*Examples*)
Decontamination / disinfection / sterilization	Instructions/Requirements for decontamination/ disinfection/sterilisation as part of validated refurbishing process

1.3.3. Mechanical and electrical refurbishment and medical equipment configuration

The refurbisher is also required to take appropriate actions when assembling and disassembling of mechanical parts, electrical parts, and equipment configuration to avoid violation of privacy rules concerning patient data stored on certain medical equipment. Table 7 indicates examples of activities, information and resources needed on mechanical and electrical refurbishment and medical equipment configuration.

Table 6. Activities, information, and resources needed on mechanical and electrical refurbishment and medical equipment configuration

ACTIVITY	**INFORMATION AND RESOURCES NEEDED** (*Examples*)
Replacing worn out parts	Instructions according to the refurbishment plan
Performing the planned applicable updates.	Instructions according to the refurbishment plan.
Customising through options and accessories within the scope of product specification.	Original manufacturer user documentation in the required language or verified translation.
Adding new and complete original manufacturer user documentation in the required language.	
Updating the MEHR to show evidence that the medical equipment was refurbished according to the specification of the equipment.	MEHR of the relevant medical equipment regarding refurbishment.
Appropriate actions to avoid violation of privacy rules concerning patient data stored on the relevant medical equipment.	Dedicated tool and validated process.

1.3.4. Cosmetic refurbishment

Cosmetic refurbishment involves improvement by cleaning and decorating medical equipment. In general, refurbishment can encompass such works as 'cosmetic' renovations (such as painting and decorating).

Table 7. Indicates examples of activities, information and resources needed on cosmetic refurbishment.

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Surface treatment, painting as needed	Instructions according to the refurbishment plan. Original paint specification of the original manufacturer regarding biocompatibility.

1.3.5. Medical Equipment Testing

Medical equipment testing includes an end-to-end analysis, assessment, and evaluation of any equipment to certify that it performs as intended, does not provide faulty information, and is fit for practical usage. Table 8 indicates examples of activities, information and resources needed on medical equipment testing.

Table 8. Activities, information, and resources needed on medical equipment testing

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Performing a system check	Instructions per original manufacturer test specifications.
Thorough checking of components and subsystems	Test medical equipment and system check procedure.
Updating the MEHR to show evidence that the medical equipment was Refurbished according to the specification of the equipment.	Equipment History Record of the relevant medical equipment regarding refurbishment.

1.3.6. Declaration of Conformity

When all necessary actions for refurbishment have been successfully completed, the refurbisher declares in the Declaration of Conformity (DoC) that the refurbished medical equipment is safe and effective as the original medical equipment. Table 9 indicates examples of activities, information and resources needed on declaration of conformity.

Table 9. Activities, information, and resources needed on declaration of conformity

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Labelling – adding date of refurbishment and GRP-Label to the genuine labelling.	GRP Labelling tool for controlled labelling (Control refurbishment label design) Refer to Clause 8.

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Updating the MEHR to show evidence that the equipment was refurbished according to the specification of the equipment.	Installed Medical equipment Database for tracking the medical equipment and ensuring optimized maintenance.
Preparing the DoC.	DoC.
Updating the MEHR to show evidence that the equipment was refurbished according to the specification of the equipment.	Equipment History Record of the relevant equipment regarding refurbishment.

1.3.7. Packaging and Transportation (After Refurbishment)

The overall objective of refurbishment is to provide the new user of the refurbished medical equipment the advantage of a medical equipment that has the same quality, performance, safety and intended use as the initial specifications. Following this objective the process after refurbishment itself such as packaging and transportation shall be identical or equivalent to the processes for new medical equipment. Table 10 indicates examples of activities, information and resources needed on packaging and transportation.

Table 10. Activities, information, and resources needed on packaging and transportation

ACTIVITY	INFORMATION AND RESOURCES NEEDED (*Examples*)
Packaging of the refurbished medical equipment.	Original manufacturer instructions for packaging.
	Original manufacturer specified tools needed for packaging.
	Original packaging material of the manufacturer e.g., frames.
	Regulation regarding packaging material.
Transportation to customer's site.	Original manufacturer instructions for transportation.
	Original manufacturer specified tools for monitoring transportation, e.g., shock and temperature indicators.

1.4. Reinstallation of refurbished medical equipment

Medical equipment refurbished according to Good Refurbishment Practice of Medical Devices (GRPMD) is intended to meet original quality, performance and safety standards based on ISO 13485 (Quality Management System), hence it is essential to follow the original manufacturer's installation procedures including site planning and preparation works. Table 11 indicates examples of activities, information and resources needed on reinstallation of refurbished medical equipment.

Table 11. Activities, information, and resources needed on reinstallation of refurbished medical equipment

ACTIVITY	INFORMATION AND RESOURCES **REQUIRED** (Examples)
Professional installation	All involved employees shall be trained according to original manufacturer requirements.
Start-up and repeated check-up of the medical equipment's performance	All involved employees shall be trained according to original manufacturer requirements.
Application training as contracted between customer and the refurbisher	All involved employees shall be trained according to original manufacturer requirements.
Hand-over of required user documentation.	User documentation.
Updating the MEHR to show evidence that the equipment was refurbished according to the original manufacturer product specifications	Equipment History Record of the relevant medical equipment.

1.5. Professional Services

The refurbisher shall provide after-sale services and support, identical to what is provided for new medical equipment. It is, thus, ensured that the user of the refurbished medical equipment will have the full necessary support of after sales services and spare parts available over the planned lifetime of the equipment. Table 12 indicates examples of activities required for professional services.

Table 12. Activities required for professional services

ACTIVITY
• Warranty equivalent to a new medical equipment • Spare parts availability • Maintenance services • Manufacturer update management • Application and user training • Financing solutions and service contracts • Qualified contact partners for product support when needed