1. Executive Summary

Governments and industries globally are increasingly recognizing the benefits of a circular economy, which aims to enhance economic and environmental sustainability. The MedTech industry may benefit from circular economy practices, particularly through the resale, refurbishment, and remanufacturing of medical devices. This practice not only extends device lifespan but also provides high-quality, affordable devices to healthcare institutions, potentially improving global patient care.

Current regulations for medical devices often do not align with broader circular economy goals. Establishing clear guidelines for refurbishment and remanufacturing is essential to ensure device safety and efficacy. This will help facilitate market acceptance of used devices and support the circular economy.

The article derives a well-defined regulatory framework, based on existing guidance and common regulatory principles that can easily be applied. Key takeaways include the distinctions between a used device, a refurbished device, and a remanufactured device, as well as the regulatory implications for those performing these activities.

2. Introduction

The economic and environmental advantages of a circular economy are increasingly recognized by governments, industries, and the public worldwide. Consequently, many countries have initiated efforts to promote the shift toward a circular economy. For instance, the European Union's Circular Economy Action Plan (2020) has become a key element of the European Green Deal. Similarly, Japan, China, the UK, and South Korea have implemented formal initiatives to advance circular economy practices. In the United States, the Environmental Protection Agency (EPA) launched its Sustainable Materials Management (SMM) Program and, in 2021, introduced the National Recycling Strategy.

For the MedTech industry, the circular economy presents significant opportunities, provided that regulatory challenges can be addressed. One such opportunity involves serving multiple customers sequentially with the same device by reselling it as a used device after it has been taken out of service. Before resale, the device may be reconditioned or refurbished, either by the original manufacturer or by a third party. This resale cycle can continue as long as the device remains serviceable and meets the applicable safety and performance standards. Regular

refurbishment can extend the device's actual lifespan well beyond the manufacturer's initial estimate, aligning with one of the core objectives of the circular economy.

Beyond the financial benefits for the industry, which can sell a device multiple times, there are advantages for the healthcare sector. Health institutions in countries with limited budgets gain access to high-quality, safe, second-hand devices, which can help improve patient care globally.

This article examines how industry could extend the lifespan of medical devices beyond their originally declared lifetime through refurbishment and remanufacturing, drawing on guidance documents issued by Malaysian authorities, the FDA, and the EU Commission

3. How to Maximize Lifetime of Medical Devices

One of the primary objectives of a circular economy is to maximize the lifespan of assets. For medical devices, this means extending their effective useful life as much as possible. Throughout this extended lifespan, it is crucial to ensure that the device continues to meet the applicable safety and performance specifications set by the original equipment manufacturer (OEM).

Figure 3.1 below illustrates various options for prolonging the life of a device at four stages of its lifecycle: during its use by the customer, in preparation for resale as a used device, as part of the refurbishment process, and during remanufacturing. Details of the options are discussed in the paragraphs 3.1 to 3.8.

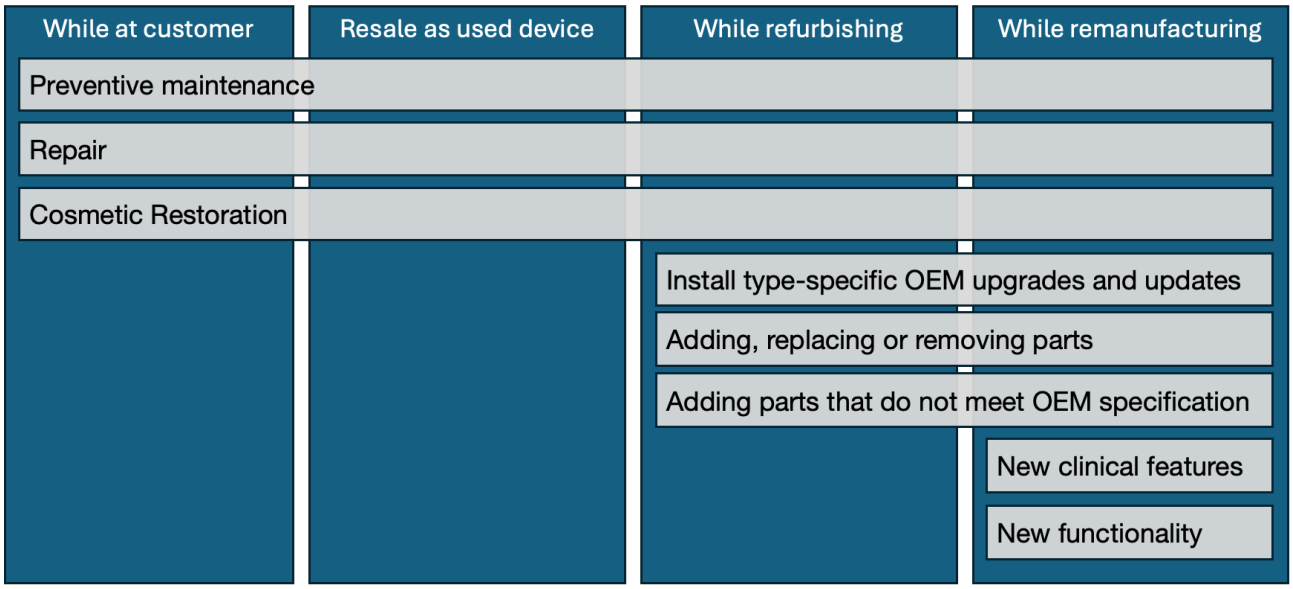

Figure 3.1: Options to extend the lifespan of a medical device and which options are allowed during four specific stages in the lifecycle of the medical device.

3.1. Preventive Maintenance

A key factor in ensuring optimal performance, safe operation, minimal downtime, and an extended useful life of a medical device is timely and adequate preventive maintenance. This maintenance typically adheres to a schedule outlined by the original equipment manufacturer (OEM).

Preventive maintenance can be performed by the customer, third-party service organizations, or the OEM itself, following the maintenance instructions provided in the OEM's labeling. For more complex maintenance tasks, the OEM may offer training and certification to individuals who demonstrate the necessary skills to perform the maintenance effectively.

Preventive maintenance is carried out while the device is at a customer, during preparation for resale as a used device, and throughout the processes of refurbishment and remanufacturing.

3.2. Repair

Repair, also referred to as corrective maintenance, takes place outside the routine preventive maintenance schedule. It involves actions aimed at restoring the normal function, safety, performance, and reliability of a malfunctioning device. This is typically achieved by replacing or repairing faulty components, followed by thorough testing to ensure the device is safe and meets the original specifications set by the OEM.

Repairs are typically carried out by the OEM or authorized third parties who have received training from the OEM and have access to all necessary information provided by the OEM on how to perform and verify repairs.

3.3. Cosmetic Restoration

Cosmetic restoration enhances or restores the device's physical appearance without affecting its functional or operational characteristics. It can be done while the device is at the customer, as part of the preparation for resale, or as part of the refurbishment and remanufacturing processes.

It may involve surface cleaning and polishing, touch-ups or repainting, replacing cosmetic components, repairing minor damage to the casing (such as dents, cracks, or scratches), and replacing worn labels or restoring faded information present on the device.

Cosmetic restoration is an integral part of maintaining the device during the full lifetime. The combination of preventive maintenance, repair and cosmetic restoration is commonly referred to as servicing a device. Servicing can be performed while the device is at a customer, during preparation for resale as a used device, and as part of the refurbishment or remanufacturing process.

3.4. Installation of Upgrades and Updates

Throughout the lifetime of a device, the OEM may release upgrades and updates for specific product types to improve software quality, enhance functionality, add clinical features, or improve reliability. Keeping the device up to date with these enhancements can extend its useful life.

If the updates or upgrades do not significantly change the intended use or add new clinical features, they can be installed during the refurbishment or remanufacturing process. However, if the intended use is altered, significant clinical features are added, or the changes have significant impact on patient risk, installing these updates or upgrades can only be done as part of a remanufacturing process.

3.5. Adding, replacing or removing Parts

During the refurbishment or remanufacturing process, components, parts, and subassemblies may be added, replaced, or removed for various reasons, such as the unavailability of original components or the use of alternative parts to improve the device's reliability or durability. These changes can contribute to extending the device's useful life.

If the OEM has authorized these modifications, they can be implemented during refurbishment or remanufacturing. However, if the OEM has not provided authorization, such changes can only be made during refurbishment if analysis and testing confirm that they do not significantly impact the device’s ability to meet the original safety and performance specifications set by the OEM, and that patient risks are not significantly increased. If the modifications affect the original

specifications or significantly increase patient risks, regulators consider the device remanufactured.

3.6. Adding Parts that are Outside OEM Specification

During refurbishment or remanufacturing, it may be necessary to add components, parts, or subassemblies that fall outside the original OEM specifications. This could occur if there are no available alternatives within the original specifications.

Typically, parts that deviate from the OEM's authorized specifications are only permitted during remanufacturing. However, by exception, this is also allowed during refurbishment, if analysis and testing demonstrate that these parts do not significantly affect the device's ability to meet the original OEM safety and performance specifications, and do not substantially increase patient risks.

3.7. Adding new Clinical Features

While a product is in use, the OEM may develop new clinical features to enhance the customer's ability to diagnose or treat patients more effectively. These features often utilize the same data already collected by the original device and may only require software updates and minor hardware modifications.

Although these new features could technically be added to existing devices, they are frequently marketed as part of a new product type, encouraging customers to upgrade to newer models.

If a refurbisher chooses to add these new clinical features during the refurbishment process, the device will be categorized as remanufactured. This triggers different regulatory requirements, including the need for a new product type and serial number, and potentially a separate regulatory submission as a remanufactured device (see section 4).

3.8. Adding new Functionality

Just as with the addition of clinical features, the OEM may develop new clinically relevant functionalities. If these functionalities are not offered as an upgrade to the existing product base and the refurbisher decides to include them, the device will be categorized as remanufactured. Consequently, the remanufactured device must adhere to different regulatory requirements (see section 4).

4. Regulatory Requirements for Used Medical Devices

The primary medical device regulatory frameworks generally do not cover the reprocessing of devices, except for those labeled by the OEM as single-use or reusable after reprocessing by the customer.

Currently, only FDA in US and MDA in Malaysia have issued guidance documents that provide direction for parties interested in reselling used devices. The MDA's guidance focuses on refurbishment, while the FDA's recently published document emphasizes remanufacturing.

Figure 4.1 below illustrates the differences and commonalities in regulatory and quality relevant aspects, as derived from the FDA and MDA guidance documents; these are linked to the stage in the device lifecycle.

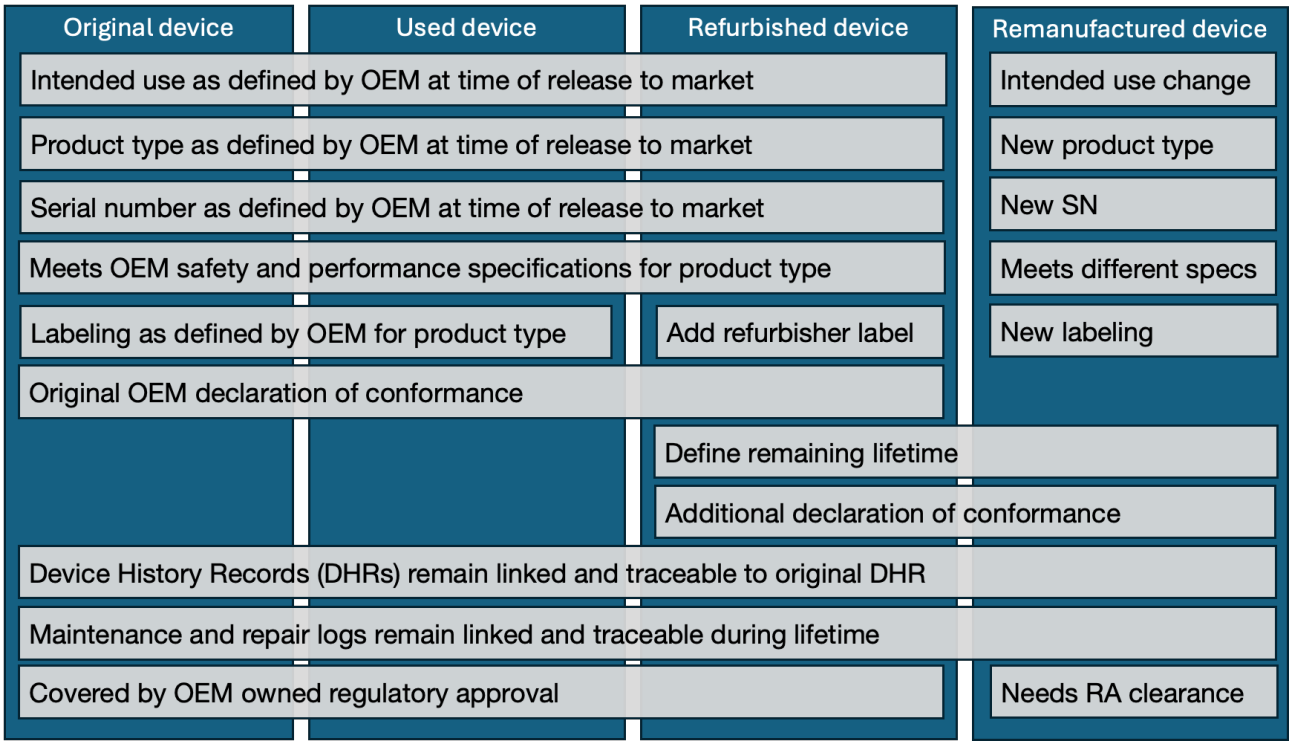

Figure 4.1: Key differences and commonalities in regulatory and quality aspects between the stages of a medical device lifecycle.

While figure 3.1 shows the various activities that are permitted at specific stages to extend the useful life of a medical device, figure 4.1 highlights the regulatory implications of carrying out those activities. Combined, these figures lay the foundation for a regulatory framework that supports a circular economy for medical devices.

The entity reselling a used medical device will assume the role of a broker, refurbisher, or remanufacturer, depending on the specific actions undertaken to prepare a device for resale. Each role carries different regulatory obligations, making it essential to clearly understand which role applies and what the associated regulatory requirements are. These aspects will be explored in detail in the following paragraphs.

4.1. Responsibilities and Obligations for Brokers

The broker selling a used medical device will typically service the device before resale, unless otherwise agreed with the buyer. This service usually includes preventive maintenance, necessary repairs, and cosmetic restoration. These tasks can either be performed by the broker or outsourced. While a warranty period and selling price may be negotiated, these details depend on the terms agreed upon between the broker and the buyer.

The broker must ensure that the device's maintenance and repair logs are updated and transferred to the new buyer. This is crucial in case of any complaints, as the OEM may need to review these logs as part of their complaint investigation process.

It's important for the broker to recognize that selling a used medical device classifies them as a distributor under medical device regulations. Consequently, they must comply with the specific regulatory requirements for distributors in their country. For EU distributors, these requirements are outlined in Article 14 of the MDR, while in the U.S., the relevant regulations are primarily found

in 21 CFR 801, 803, 806, 807, 820, and 822. Other countries may also have their own specific requirements for distributors.

4.2. Responsibilities and Obligations for Refurbishers

The key difference between reselling a used device and refurbishing one lies in the goal of refurbishment: to restore a used device to a condition comparable to new. This process may include installing device-specific upgrades and software updates released by the OEM after the device was put on the market. However, these upgrades and updates can only be installed if the intended use remains the same as originally defined, and the safety and performance characteristics set by the OEM are not significantly altered.

It is crucial for the refurbisher to have access to the latest, up-to-date Device History Record, including maintenance and repair logs, and the Device Master Record. Besides that, it is essential that the refurbisher thoroughly understands the device. For this reason, refurbishment often occurs at the OEM or by a third party trained and authorized by the OEM.

The refurbishment process must follow work instructions and procedures that are part of a quality management system that complies with ISO 13485.

A typical refurbishment process involves several stages:

1. Selection of Medical Devices for Refurbishment

   When considering the refurbishment of a medical device, it is essential to evaluate the type, configuration, and condition of the used device, along with its age, upgradeability, and the device family's lifecycle stage. Access to the device's maintenance and repair logs, as well as the OEM's servicing information, is crucial. The device family's lifecycle stage is particularly important as it relates to the availability of spare parts, which determines the device's serviceability and remaining useful life. Devices nearing the end of the manufacturer's serviceability period may not be viable candidates for refurbishment.

2. Cleaning and Decontamination

   For devices that may have been exposed to human tissue or fluids, thorough decontamination and cleaning according to the manufacturer's instructions are essential. This step minimizes the risk of pathogen exposure to those handling the device during refurbishment.

3. Stripping the Returned Device

   Upon arrival, the technical condition of the device must be assessed in detail. This typically requires dismantling the device into its parts, components, and subassemblies (collectively referred to as "parts"). This disassembly allows for a thorough evaluation of each part's suitability for reuse.

4. Assessing the Suitability of Stripped Parts

   After disassembly, the technical state and remaining lifespan of each part can be estimated. Access to reliability data for individual parts is beneficial, although OEMs may not always share this information with third parties. This stage also involves documenting and planning any necessary repairs or preventive replacements. Parts deemed unsuitable for reuse must be labeled, discarded, and sent to appropriate recycling facilities.

5. Reconditioning and Repair of Stripped Part

   Parts identified for reuse are reconditioned and repaired as necessary to meet the OEM's specifications. All rework and repairs must follow documented work instructions based on

the OEM's service and repair instructions. The resulting rework and repair records must be maintained and included in the Device History Record (DHR) of the refurbished device.

6. Release of Refurbished Parts for Reuse

   Once refurbished parts are verified to meet the OEM's specifications, they are released for reuse. Depending on the refurbishment model, these parts can either be reassembled into the original device, supplemented with new components as needed, or added to an inventory pool where they can be used to assemble other refurbished devices.

7. Assembly of the Refurbished Device

   The refurbished device must be assembled according to the OEM's Device Master Record to ensure consistent build quality. New original spare parts may be used when refurbished parts are unavailable, especially for worn-out components. During assembly, regulatory-approved upgrade kits and software updates may be installed, provided they do not alter the device's original intended use or significantly change its safety and performance characteristics. The Device History Record must be updated to reflect the configuration of the rebuild device.

8. Testing the Assembled Device

   The refurbished device must undergo testing according to the original OEM's specifications and Device Master Record to ensure it meets the criteria for "as new" condition. Test results are documented in the Device History Record.

9. Labeling the Refurbished Device

   Since the refurbished device retains its original product type, serial number, and manufacturing year, it is important to inform the customer of the refurbishment. Most regulations require the addition of a refurbishment label, placed next to the original label, indicating the year of refurbishment and the refurbisher's identity.

10. Issuing a Declaration of Conformity

    Finally, the Device History Record is completed with a Declaration of Conformity, in which the refurbisher attests that the refurbished device is as safe and effective as the original. The refurbisher must keep the Device History Record in its records or provide it to the OEM.

Once the refurbishment process is complete, the medical device can be made available again to the market, accompanied by its updated maintenance and repair record, and the declarations of conformity of the OEM and refurbisher. When the refurbisher sells the device, they also assume the role of a distributor and must comply with the relevant local regulations for distributors, like a broker (see paragraph 4.1).

4.3. Responsibilities and Obligations for Remanufacturers

The primary distinction between refurbishment and remanufacturing lies in the extent of changes made to the OEM originally defined device's performance, safety specifications, or intended use. Remanufacturing involves substantial modifications that alter these aspects, whereas refurbishment aims to restore the device to a state similar to new. The process steps in a remanufacturing process are similar to the refurbishment process. In European regulations, remanufacturing is often referred to as "full refurbishment".

When a device is categorized as remanufactured, it is treated as a new device from a regulatory perspective. This means it requires a new product type, a new serial number, and new labeling.

The remanufacturer becomes the legally accountable manufacturer and must adhere to the complete regulatory approval process in the country where the device will be marketed.

An exception to this requirement occurs if the OEM itself is the remanufacturer and modifies the device into an already approved other product type of the OEM. For instance, if a device consists of modules and the product type is determined by the combination of these modules, adding an originally not included module to a refurbished device will be considered remanufacturing. However, if the OEM has regulatory approval for the new module combination, additional regulatory approval may not be required.

Due to the serious implications of misclassifying a remanufacturing process – in case of a mistake you may put unapproved medical devices on a market - it is essential to have a well-documented decision-making process. This process should assess and carefully document whether the changes affect the intended use, increase patient risk, or have a significant impact on the ability to meet the OEM's safety and performance specifications.

The FDA's latest guidance document on remanufacturing outlines when changes are considered significant. Similarly, European guidance under MDR, as detailed in MDCG 2020-3 rev 1, provides criteria for significant changes that largely overlap with the FDA guidance on remanufacturing. Table 4.1 below integrates both documents to offer a comprehensive set of criteria for changes that will recategorize refurbishment into remanufacturing.

Topic	**Changes that recategorize refurbishment into remanufacuring**

Intended use	- Change from single use to reusable
	- Addition or removal of contraindications
	- Additional or new
	  o indication for use
	  o target population,
	  o user group,
	  o clinical applications,
	  o anatomical site,
	  o delivery pathway, or
	  o deployment method.

Design	- Changes that reduce significantly the lifetime of the device, - Widen specifications on dimensions, performance, or safety outside the OEM defined tolerances, - Changes to the control mechanisms, operating principles, or energy types, - Changes that significantly affect the use or usability of the device, - Changes requiring new clinical data to validate performance or safety, - Changes that violate conditions set for the existing regulatory approval, or - Changes that conflict with international voluntary standards.
Software	- Adding, or changing critical hardware components, - Any change in software configurations except to:

	○ Reinstall software released by the original manufacturer, ○ Install updates and upgrades authorized by the original manufacturer, ○ Install OEM authorized cybersecurity updates, ○ Download or access system logs, diagnostic and repair information, ○ Perform data backup and recovery operations, ○ Revert software to a previous configuration, or ○ Run diagnostic software to verify hardware, scan for virus, malware and other cybersecurity threats.
Materials and substances	- Changes that have significant impact on biocompatibility data that supported original regulatory approval, - Changes that have significant impact on the reprocessing instructions that supported the original regulatory approval, or - Changes to medicinal substances or its excipient.
Sterility Assurance	- Changes to sterilization methods, - Changes which adversely affects sterility assurance levels, - Changes in packaging design that affect sterility, stability, or the micro-biological state of the device, or - Shelf life extensions validated by protocols that are not approved by regulators.
Risk	- Changes introducing new hazards or hazardous situations, - Changes that increase significantly the probability of harm for an existing risk, - Removing, modifying or bypassing a safety feature, - Changes that negatively affect the benefit/risk ratio, or - Changes for which the cumulative effect significantly impacts the safety or performance characteristics of the device.

Table 4.1: Overview of what type of changes are considered significant and cannot be done as part of refurbishment based on a combination of European and FDA guidance documents.

5. Conclusions and Recommendations

Current medical device regulatory frameworks have largely remained separate from broader political efforts aimed at promoting a circular economy. As a result, companies and third parties interested in selling used, refurbished, or remanufactured devices often face a lack of clear regulatory guidance.

Establishing clear requirements for refurbishment and remanufacturing is crucial for ensuring that these devices are as safe and effective as new ones. Such clarity will facilitate the acceptance of used devices in markets that currently reject refurbished and remanufactured products.

This article demonstrates that a comprehensive framework for extending the useful life of medical devices can be developed from existing guidance on refurbishment and remanufacturing. Such framework supports the goals of the circular economy while providing robust assurances of patient safety, comparable to new medical devices.

Key takeaways for resale, refurbishment, or remanufacturing of medical devices include:

- A used medical device is a device that has been taken out of service and is reintroduced to the market after undergoing maintenance, repair, and/or cosmetic restoration.
- A refurbished medical device is a device that is restored to a condition comparable to new.
- A remanufactured medical device differs from the original OEM-released product and is therefore treated as a new medical device by regulators.
- Selling used, refurbished, or remanufactured devices qualifies you as a distributor, necessitating compliance with relevant regulatory requirements.
- Refurbishment and remanufacturing require access to the original Device History Record and Device Master Record. These processes should therefore be conducted either by the OEM or by third parties authorized by the OEM.
- Refurbishers and remanufacturers must implement a Quality Management System that complies with ISO 13485.
- Remanufacturers take over the role of the legally accountable manufacturer from the OEM and must follow the necessary processes to obtain regulatory approval.

6. References

[1] Good refurbishment practice of medical device (GRPMD); MDA/GD/0029 January 2016

[2] Refurbished Medical Device – Requirements; MDA/GD/0060 January 2022

[3] Remanufacturing of Medical Devices; FDA guidance, May 10, 2024

[4] Medical Device Regulation; (EU) 2017/745, May 5, 2017

[5] Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD; MDCG 2020-3 rev 1, May 2023

Kees den Besten, 03 September 2024