Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Single-use medical devices:

UK guidance on re-manufacturing

June 2016

Contents

1 Executive summary 3
2 Introduction 4
3 Details of re-manufacturing single-use devices 5
4 Legal implications, negligence and regulatory requirements 8
5 Healthcare facility responsibilities 8
6 Glossary 9
7 References 11

© Crown copyright. Published by the Medicines and Healthcare Products Regulatory Agency

1 Executive summary

This document applies in the UK only, and sets out the UK's position on **re-manufacturing single-use devices** (SUDs).

The document makes a clear distinction between a re-manufactured SUD and devices that are reprocessed or fully refurbished (see glossary). The MHRA has separate guidance on reprocessing of single-use devices.

Main points:

- Single-use devices may be re-manufactured for use in the UK. However, the re-manufacturer, prior to placing their device on the UK market or to putting it into service, should meet all relevant criteria under the appropriate medical devices directive [1, 2] and place a CE mark on their product to declare conformity with that directive.

- The re-manufacturer accepts all liabilities and obligations for the re-manufacturing of the single-use device. The intended use of the re-manufactured device should not differ from the intended use of the original product.

- The supply of a particular re-manufactured SUD should be through a closed loop contract between the re-manufacturer and the healthcare institution (e.g. hospital, clinic). At no time should a re-manufacturer or healthcare institution sell or provide a re-manufactured SUD to any other third party.

- A re-manufactured single-use device should only be used on an individual patient during a single procedure and after that use the SUD should be returned to the contracted re-manufacturer.

- The packaging or device must have the symbol below, which means do not reuse / use only once / single-use only.

This document is aimed at:

- all companies who re-manufacture medical devices that were originally 'single use'.
- notified bodies
- UK trade associations
- all providers of medical devices e.g. NHS Supply Chain, re-manufacturers.
- chief executives and managers of institutions where medical devices are used.
- healthcare institutions and professionals who use medical devices.

2 Introduction

Re-manufacturing of single-use devices (SUD) and similar processes to re-manufacturing have existed outside of the UK for a number of years. The MHRA has published this document as we are aware that a number of companies now wish to introduce SUD re-manufacturing to the UK.

The medical devices directives [1, 2] do not explicitly permit re-manufacturing or re-processing. Anyone who re-manufactures or re-processes a device assumes the full legal responsibilities and liabilities of a manufacturer. This document sets out the MHRA's position for advising those who decide to place re-manufactured single-use devices on the market in the UK.

The re-manufacturing terminology used and expectations outlined in this guidance may differ from other EU and international regulators. The MHRA makes a clear distinction between a re-manufactured SUD and devices which are reprocessed or fully refurbished (see glossary).

The MHRA has issued separate guidance on reprocessing of single-use devices.

Re-manufacturing SUDs in line with this guidance involves a re-manufacturer confirming the conformity of the re-manufactured SUD with the relevant medical devices directive and placing a CE mark on their product. This should be done **before** placing the product on the market or putting it into service.

The re-manufacturer should demonstrate that the re-manufactured device can clearly meet all appropriate requirements of the relevant medical devices directive. The re-manufacturer should confirm validity and surety of all manufacturing processes and accepts all liabilities and obligations for the re-manufactured SUD.

We expect any healthcare institution that chooses to use re-manufactured single-use medical devices to have a contract with a specific re-manufacturer. Further information is in Section 5 of this document.

Note: All class I medical devices are excluded from this policy The MHRA considers that class I products should not be re-manufactured as there would be no external or independent assessment of CE mark compliance.

The European Union (EU) legislation on medical devices is currently being revised. When this is finalised, the MHRA will review this guidance and update it if necessary.

3 Details of re-manufacturing single-use devices

A re-manufacturer will need to assess, using appropriate evidence, that the single-use device is appropriate for re-manufacturing, as not all SUDs will be suitable.

The notified body should verify that the re-manufactured single-use device clearly meets **all appropriate criteria** of the relevant medical devices directive in terms of performance and safety. The notified body should confirm validity and surety of all manufacturing processes (design processes where applicable), and that they meet the regulatory requirements pre- and post-market.

Through use of clinical and technical testing and supporting evidence the re-manufacturer shall establish the maximum number of re-manufacturing cycles to which the device will be subjected while maintaining all device functionality, performance and safety parameters.
It is the re-manufacturer's responsibility to track the number of times the device is re-manufactured and reused.
After the first use of the single-use device, the original equipment manufacturer (OEM) is no longer responsible for the product if it is re-manufactured.

When the re-manufactured SUD no longer meets specification, or the defined number of re-manufacturing cycles has been reached the device shall be disposed of by the re-manufacturer or healthcare institution. If during the re-manufacturing process the device fails to meet any aspect of functionality, performance or safety, the company shall dispose of the device.

The re-manufacturer is responsible for providing, to the healthcare facility, all appropriate containers or returns packaging. The re-manufacturer's responsibility for the device starts when the healthcare facility places the used product into the re-manufacturer's container or returns package, which would be sited at the healthcare facility.

A re-manufacturer is responsible for ensuring that used SUDs are returned to them. The re-manufacturer shall ensure that returned SUDs do not include items that may have been re-manufactured or reprocessed by a different facility. At no time should a healthcare institution or re-manufacturer sell or provide a re-manufactured SUD to any other third party.

The re-manufacturer accepts all liabilities and obligations for the re-manufacturing of the single-use device. For example:

- technical documents
- decontamination, cleaning, sterilization and bioburden
- labelling
- risk management
- post-market surveillance.

Note: This is not an exhaustive list of examples, and does not replace the legal requirements as set out in the directives, but merely gives guidance on areas.

3.1 Technical documents

The re-manufactured product shall meet the safety and performance requirements of the relevant directive. The re-manufacturer should prepare and maintain full technical documentation including clinical evidence. Clinical evidence may either be presented on the outcomes from the re-manufacturer's clinical trial, or through detailed information on equivalence to the OEM's device.

The intended use of the re-manufactured device should not differ from the intended use of the original product.

For all re-manufactured SUDs belonging to class III, class IIa and IIb, the design of the medical device and its compliance with the relevant medical devices directive and quality assurance system should be examined by a notified body. The notified body reviews of class IIa and IIb re-manufactured SUDs should **not** be undertaken on a representative basis.

The manufacturer or the EU authorised representative must keep copies of the technical documentation for a period of at least 5 years. In the case of implantable devices the manufacturer must keep the documentation for at least 15 years after the last product has been placed on the market.

3.2 Decontamination, cleaning, sterilization and bioburden

As part of the bioburden assessment the re-manufacturer should have validated SUD decontamination, cleaning and sterility processes.

Validation should include testing which demonstrates removal of cytotoxicity, sensitisation, endotoxins, prion/TSE, irritation, toxic and leachable materials. Testing should be undertaken in line with current standards.

The re-manufacturer should also have systems in place to ensure there is no cross-contamination between devices from different healthcare institutions or re-manufacturing lines.

To ensure on-going integrity of the decontamination and sterility processes, and as part of the bioburden verification, the re-manufacturer should undertake periodic audits of their processes. The audits should follow international and national standards and guidance from appropriate governing bodies.

3.3 Labelling

Packaging and instructions for use should clearly state that the SUD is a re-manufactured version of the original.

To ensure device users know who re-manufactured the SUD and are clear who to report device problems to, the re-manufacturer's identifiers should clearly display:

- on the label and packaging: the re-manufacturer's name, full address and serial number or unique identifier
- on the device: the re-manufacturer's own unique identifiers, as applicable

To maintain traceability of the original manufacturer's device and as part of risk mitigation, the re-manufacturer should consider the need for the inclusion, on the device label and packaging, the original manufacturer's identifiers, specifically the company name, full address and serial number or unique identifier

The MHRA has responsibility for ensuring safe products in the UK. We have not considered the intellectual property of the OEM or their permission for their name/product being used.

All legal obligations under the relevant directive should be followed. As the device is for single use, once it has been re-manufactured it should bear the symbol:

3.4 Risk management

As part of ensuring good quality systems the re-manufacturing company should demonstrate that they comply with the standard EN ISO 14971 Medical devices: application of risk management to medical devices [3].

The notified body should assess compliance with the harmonised standard for risk management. This standard defines the requirements of risk management systems for medical devices, detailing best practices throughout the life cycle of the re-manufactured single-use device, including a risk analysis identifying all possible risks and associated mitigation strategies.

3.5 Post-market surveillance

Under the EU guidelines on a Medical Devices Vigilance System [4], SUD re-manufacturers have responsibilities for adverse event reporting.

Within the framework of quality management and as part of post-market surveillance activities, the re-manufacturer should have a continuous monitoring process to identify any problems associated with the re-manufactured devices and changes the OEM makes to components, materials or specifications. There are a number of routes for doing this:

- continuous market observations or safety information (e.g. Field Safety Notices) published by the OEM
- published FDA marketing clearance or safety information
- safety information from competent authorities
- information from end users
- incoming goods inspection for all devices
- electrical, material, performance and safety assessments conducted on all devices during re-manufacturing
- manufacturing and outgoing goods inspections for all devices.

Under post-market surveillance, the re-manufacturer is responsible for managing product safety issues associated with their re-manufactured product and any product safety notification or recall that the OEM has implemented and which has an impact on a re-manufactured device.

In addition to the previous points:

- if the OEM makes any design changes to the SUD, the re-manufacturer should assess the significance of the change and confirm through their own testing if modifications are required to the re-manufacturing production process to accommodate the OEM design. If there is an OEM modification that results in a safety-related action for re-manufactured devices, the re-manufacturer is responsible for completing the safety related action.
- if the OEM recall their devices, or specific batches, the re-manufacturer should undertake a risk assessment to identify their own actions. The re-manufacturer should clearly document within their technical documentation what subsequent action has or hasn't been undertaken by them.
- if during re-manufacturing of the device a problem is identified and it 1) concerns the OEM design and 2) affects the safety of the OEM's device, the re-manufacturer should inform the OEM of the issue.

The re-manufacturer is also expected to have post-market surveillance in place to:

- trace the re-manufactured device to the batch or serial number of the original device

- maintain a record of who was supplied with re-manufactured devices. This is to ensure any regulatory actions can be carried out quickly and effectively.

4 Legal implications, negligence and regulatory requirements

The medical devices directives [1, 2] do not explicitly permit re-manufacturing or re-processing. Anyone who re-manufactures or re-processes a device assumes the full legal responsibilities and liabilities of a manufacturer.

The re-manufacturing terminology used and expectations outlined in this guidance may differ from other EU and international regulators.

In the UK anyone who re-manufactures an SUD has the same legal obligations under the medical devices directives [1, 2] as the original manufacturer of the device.

The medical devices directive [1] indicates the following:

(i) In the definitions: ‘single use device’ means a device intended to be used once only for a single patient;

(ii) If the device is intended for single use, it must have an indication of that fact. A manufacturer's indication of single use shall be consistent across the European Union.

5 Healthcare facility responsibilities

A healthcare facility that uses re-manufactured single-use devices should have a contract with a re-manufacturer. A healthcare institution may have contracts with different re-manufactures for different single-use devices.

As part of the contract the healthcare facility should always return the used SUD to the **same** re-manufacturer.

The healthcare facility should only use a re-manufactured SUD on an individual patient during a single procedure.

Once the re-manufactured product is used the healthcare facility should either place the used product into the re-manufacturer’s containers or returns package which would be sited at the healthcare institution.

As part of the legislative conformity assessment the re-manufacturer will have established the maximum number of times a device can be re-manufactured. When the device can no longer be re-manufactured it will be destroyed by the re-manufacturer. The healthcare facility **should not** sell or provided the devices to any other third party.

At no time should a re-manufactured single-use device be **reprocessed** by the healthcare institution, or any third party.

Any problems associated with the re-manufactured SUD should be reported to the re-manufacturer.

6 Glossary

Bioburden [5] – population of viable microorganisms on or in a product or sterile barrier system

Cleaning – a process that physically removes contamination but does not necessarily destroy micro-organisms.

Closed loop – where a re-manufactured SUD is supplied and returned, under contract, between the SUD re-manufacturer and healthcare facility. The re-manufactured SUD **should not** be sold or provided to any other third party outside the contracted re-manufacturer and healthcare facility.

Decontamination – a process which removes or destroys contamination and thereby prevents micro-organisms or other contaminants reaching a susceptible site in sufficient quantities to initiate infection or any other harmful response. Three processes of decontamination are commonly used: cleaning, disinfection, sterilization.

Disinfection – a process used to reduce the number of viable micro-organisms but which may not necessarily inactivate some bacterial agents, such as certain viruses and bacterial spores.

Endotoxin – a lipopolysaccharide, formed by the breakdown of the cell wall of Gram-negative bacteria. Bacterial endotoxins can be active even if the bacteria from which they are released are killed.

Fully refurbishing – the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with the medical devices directives, combined with the assignment of a new lifetime to the refurbished device.

Healthcare institution – a device owner who makes use of the device e.g. a hospital trust.

Manufacturer – The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under its own name. This can be a company or an individual.

Medical device – Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of:

- control of conception
- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability
- investigation, replacement or modification of the anatomy or physiological process.

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

Place on the market – The first making available in return for payment or free of charge of a device, (other than a device intended for clinical investigation) with a view to distribution and/or use in the market, regardless of whether it is new or refurbished.

Putting into service – the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose
(Note: a re-manufactured SUD is considered to be put into service for the first time)

Original Equipment Manufacturer (OEM) – the natural or legal person who manufactures a device or has a device designed, manufactured and markets that device under their name or trademark.

Re-manufacturing (of single-use devices) – The following is the UK's definition of re-manufacturing of single use devices (SUDs):
Re-manufacturing is where a company obtains a CE mark for the re-manufacturing of single-use devices.

A re-manufactured SUD may not necessarily have components changed in all re-manufacturing episodes. However, prior to placing on the market or putting into service, the device will be cleaned, disinfected and sterilized and be tested against the re-manufacturer's specifications to ensure the SUD continues to operate safely and as intended.

In the UK a re-manufacturer of single-use devices must clearly meet all criteria of the relevant medical devices directives [1, 2]. The re-manufactured, single-use device should carry a CE mark, obtained by the re-manufacturing company, specifically for the commercial re-manufacturing of single-use devices.

Re-manufacturing of single-use devices is different to reprocessing.

Reprocessing – where a person, institution or organisation undertakes processes on a used device in order to allow the safe reuse of the device. The processes may include cleaning, disinfection, sterilization, as well as testing and restoration of the technical and functional safety of the used device. Re-processing should only be on a multi-use medical device, in line with the manufacturer's instructions for use.

The reprocessor is **not** expected to undertake a conformity assessment and place their own CE mark on the device prior to placing the device on the market or putting into service.

Where a reprocessor reprocesses an SUD contrary to the manufacturer's instructions, there might be nothing to show that the device has been used before, nor any indicators that the reprocessing method is effective. If the reprocessed SUD doesn't work as originally intended, there would be questions about who is liable for it.

The medical devices directive [1, 2] does not permit reprocessing. Anyone who reprocesses a medical device has the legal responsibilities and liabilities of a manufacturer.

The MHRA advises **against** reprocessing single-use devices. See our separate guidance document.

Reuse – Another episode of use, or repeated episodes of use, of a medical device, which has undergone some form of reprocessing or has been fully refurbished between each episode.

Single-use – this expression means that the medical device is intended to be used on an individual patient during a single procedure. It is not intended to be reprocessed and used on another patient. The single-use device should either be discarded, or if appropriate, returned to a re-manufacturer of single-use devices.

The symbol below is used on medical device packaging indicating ‘do not reuse’ and may replace any wording.

Some single-use devices are marketed as non-sterile but require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.

Symbol reproduced from BS EN ISO 15223-1:2012 ‘Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied’. Permission to reproduce extracts from British Standards is granted by BSI Standards Limited (BSI).

Sterilization – A process used to make an object free from all viable micro-organisms including viruses and bacterial spores.

Validation – Documented procedure for obtaining and interpreting the results required to establish that a process will consistently yield a product complying with predetermined specifications.

7 References

1. Council Directive 93/42/EEC concerning Medical Devices, OJ L169 of 12 July 1993 last amended by Directive 2007/47/EC.

2. Council Directive 90/385/EEC concerning Active Implantable Medical Devices, OJ L189 of 20 July 1990 last amended by Directive 2007/47/EC.

3. ISO 14971 Medical devices: application of risk management to medical devices

4. The European Commission Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 8, January 2013

5. ISO/TS 11139 Sterilisation of health care products: vocabulary