Single-use medical devices: UK guidance on re-manufacturing

Contents

1 Executive summary

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

Key points:

- Anyone who re-manufactures a single-use device has the same legal responsibility for it as the original manufacturer.
- Single-use devices may be re-manufactured for use in the UK. However, the company must meet all relevant criteria under the appropriate Medical Devices Directive and place a CE-mark on their product to attest conformity with the legislation.
- A re-manufactured single-use device should only be used on an individual patient during a single procedure.
- The packaging or device must have the symbol below, which means do not reuse / use only once / single-use.

This document is aimed at:

- All companies who re-manufacture medical devices that were originally 'single use'.
- All providers of medical devices.
- Chief executives and managers of organisations where medical devices are used.
- Healthcare professionals who use medical devices.

2 Introduction

There is a clear difference between a re-manufactured single-use device (SUD) and a reprocessed one. We outline the differences below.

Re-manufacturing SUDs involves a company, prior to placing the product on the market, confirming the conformity of the re-manufactured SUD to the relevant Medical Device Directive [1] and place a CE-mark on their product. The company must demonstrate, to the satisfaction of a notified body, that the re-manufactured device can clearly meet all appropriate criteria of the relevant Medical Devices Directive]. The company must confirm validity and surety of all re-manufacturing processes and accepts all liabilities and obligations for the SUD.

Note: 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.

We expect any healthcare organisation that chooses to use re-manufactured single-use medical devices to have a contract with a specific re-manufacturer. As part of the re-manufacturing contract, the healthcare organisation should always return the SUDs to the same re-manufacturing company.

Reprocessing SUDs is where a person or organisation, contrary to the manufacturer's instructions, cleans and sterilizes the medical device and it goes back into the healthcare environment. The reprocessed medical device has all the markings of the original manufacturer. 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 medical device doesn't work as originally intended, there would be questions about who is liable for it.

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

The MHRA is aware that a number of companies are re-manufacturing SUDs and placing them back on the market and that these devices comply with the requirements of the relevant Medical Devices Directive and have a legitimate CE mark.

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

The re-manufacturing company has to demonstrate to a notified body 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 company also has to confirm to the notified body the validity and surety of all re-manufacturing processes, and that they meet all post-market surveillance requirements.

The single-use device may be re-manufactured, by the same company, for a limited number of times. The number of re-manufacturing cycles will have been validated, by the re-manufacturer, to ensure all device functionality, performance and safety parameters are

being met. It is the re-manufacturer's responsibility to track the number of times the device is re-manufactured and reused. Once the re-manufacturing cycles have been reached the device must be disposed of by the re-manufacturer. If during the re-manufacturing process the device fails to meet any aspect of functionality, performance or safety, the company must dispose of the device.

The re-manufactured single-use device must clearly display all the original manufacturer's identifiers. The re-manufacture company must also clearly display their own identifiers on the device, i.e. company name, full address and serial number or unique identifier. Packaging and instructions for use must clearly state that this product has been re-manufactured from the original.

After the first use of the single-use device, the original equipment manufacturer (OEM) is no longer responsible for the product if it is not disposed of. The healthcare facility can return used SUDs to their contracted single use device re-manufacturer. The re-manufacturer's responsibility for the device starts when the healthcare facility places the used product into the re-manufacturer's 'bins' or "return's package" which would be sited at a hospital or clinic.

If a re-manufacturer receives a single-use device from a hospital which has any indication that it has been re-manufactured or reprocessed by a different facility, they should dispose of the product.

The re-manufacturer accepts all liabilities and obligations for the re-manufactured single-use device. For example:
(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)

Technical documents

The re-manufacturer will need to show that the re-manufactured SUD will continue to perform as originally intended by the OEM, without additional risk to the patient or end user. Before applying to a notified body for the CE mark, the re-manufacturer must have technical documents and where applicable clinical evidence about the device that shows how the device conforms to the requirements of the relevant Directive.

For all medical devices belonging to class III, and for medical devices belonging to class IIa and IIb on a representative basis, the design of the medical device and its compliance with the Essential Requirements and quality assurance system must be examined by a notified body.

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.

Decontamination, cleaning, sterilization and bioburden

As part of the bioburden assessment the re-manufacturer must have validated SUD decontamination, cleaning and sterility processes. The processes should include tests for cytotoxicity, sensitisation, endotoxins, prion/TSE and irritation. Each test should also screen for the presence of toxic and leachable materials.

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

Labelling

The labelling must clearly state that the medical device is a re-manufactured device. The re-manufacturer's name, full address and authorised representative (if applicable) should be clearly stated. For further identification should the OEM undertake a and safety action, the labelling should have the original manufacturer's name and product's serial number or unique identifier.

The MHRA is concerned with having safe products available for use. 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 and if this device is for single use once re-manufactured it should bear the symbol:

Risk management

As part of ensuring good quality systems the re-manufacturing company should show the notified body that they comply with the standard ISO 14971 'Risk Management for Medical Devices' [2]. 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.

Post-market surveillance

The SUD re-manufacturers are subject to the same requirements for adverse event reporting as the OEM.

Within the framework of quality management and as part of post-market surveillance activities, the re-manufacturer must have a continuous monitoring process to identify any 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. FSNs) published by OEM
- published FDA approvals 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.

The re-manufacturer's post-market surveillance team is responsible for managing 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:

- should the OEM undertake any design changes to the SUD, the re-manufacturer must 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 completion of the safety related action.
- if during re-manufacturing of the device a problem is identified which affects the safety of the OEM's device, the re-manufacturer must inform the OEM of the issue.

The re-manufacturer would also be expected to have post-surveillance systems in place to:

- trace the re-manufactured device to the batch or serial number of the original device
- record who the supply the re-manufactured device to should any regulatory action be required

4 Legal implications, negligence and regulatory requirements

Medical devices re-manufactured and placed on to the market in the UK and in the rest of the European Union (EU) are subject to specific legislation.

The Medical Devices Directive 93/42/EEC states the following:

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

(ii) A manufacturer's indication of single use must be consistent across the Community;

(iii) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request.

It is clear that anyone who re-manufacturers a SUD and passes it to a separate legal entity for use has the same legal obligations under the Medical Devices Regulations [1] as the original manufacturer of the device.

5 Healthcare facility responsibilities

A healthcare facility that uses re-manufactured single-use devices must have a contract with a re-manufacturer. The healthcare facility should always return the product to the same re-manufacturing company. As part of the legislative conformity assessment the re-manufacturer will have established the maximum number of cycles a device can be re-manufactured. When the device can no longer be re-manufactured it will be destroyed by the re-manufacturer.

At no time should a re-manufactured single-use device be **reprocessed** by the hospital, or any third party. Once the re-manufactured product is used the healthcare facility should

either place the used product into the re-manufacturer’s ‘bins’ or “return’s package” which would be sited at a hospital or clinic.

Glossary

The following terms have been defined for the purpose of this bulletin:

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

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 – Is a toxin 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.

Legal entity – An individual, institution or organisation that has its own existence for legal or tax purposes e.g. a corporation, partnership or 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.

Placing 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.

Re-manufacturing (of single-use devices) – a re-manufacture of single-use devices must clearly meet all criteria of the relevant Medical Devices Directives. The re-manufactured, single-use device must 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. Re-manufacturing is where a company obtains a CE mark for the commercial re-manufacturing of single-use devices.

Reprocess – To make good the device for reuse by any or a combination of the following processes:

- cleaning
- disinfection/decontamination
- sterilization
- refurbishment
- repackaging.

Note: the manufacturer of reusable devices should provide validated reprocessing instructions along with the device.

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

Single-use – The expression ‘single-use’ 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 980:2003 ‘Graphical symbols for use in the labelling of medical devices’, with permission from: BSI, 389 Chiswick High Rd, London W4 4AL. E-mail cservices@bsi-global.com, tel: 020 8996 9001).

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

References

1. The Medical Device Directives
   - Directive 93/68/EEC [CE Marking]
   - Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
   - Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma
   - Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices
   - Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
   - UK Regulations:The Medical Devices Regulations 2002. Statutory Instrument 2002 No. 618 (as amended)

2. ISO 14971 ‘Risk Management for Medical Devices’