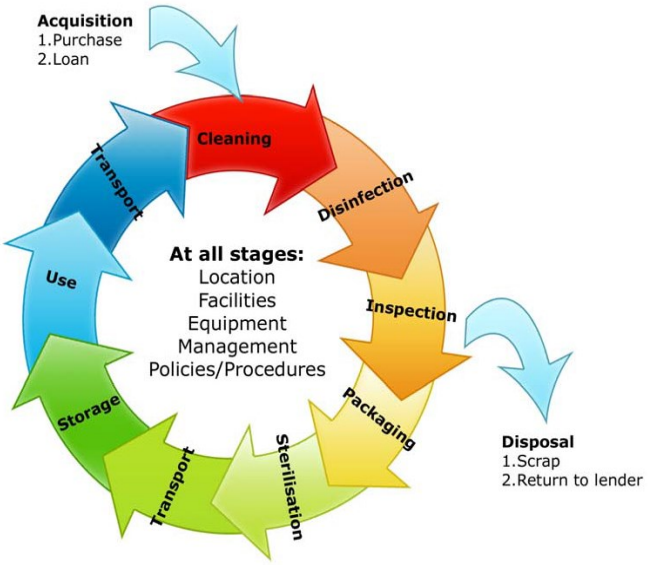
Health Service Executive
Guidance for the Application of Standards and Recommended Practices for Local Decontamination Units (LDUs) in Primary Care, Dental, Podiatry and GP Practice



Directorate:	Quality Improvement Team
Title:	HSE Guidance for the Application of Standards and Recommended Practices for Local Decontamination Units in Primary Care Dental, Podiatry and GP Practice
Document Reference Number:	QPSD-GL-027-1 .1
Version Number:	1.1
Document Purpose:	Guidance for the Implementation of Standards & Recommended Practices for Decontamination of Reusable Invasive Medical Devices in Primary Care.
Author:	HSE National Quality Improvement Team Decontamination Advisor
Approval Date:	June 2019
Target Audience:	All relevant staff in the public health service who work in and/or are involved in the decontamination of Reusable Invasive Medical Devices in Primary Care.
Description:	HSE Guidance for the Application of Standards and Recommended Practices for Local Decontamination Units in Primary Care Dental, Podiatry and GP Practice are based on current legal, regulatory requirements and professional best practice.
Superseded Docs:	HSE Guidance for the Application of Standards and Recommended Practices for Local Decontamination Units in Primary Care Dental, Podiatry and GP Practice (Version 1, 2016)
Revision Date:	Sept 2024
Contact Details:	Caroline Conneely, Decontamination Advisor National Quality Improvement Team , Health Service Executive, Dr Steeven's Hospital, Dublin **Eircode:** D08 W2A8 Email: caroline.conneely1@hse.ie

(***Note :*** *This document is based on best available international evidence at the time of guidance development. This document will not be updated until 2024 unless there are significant legislative or regulatory changes that many impact on practice, facilities, equipment or testing requirements in the interim period).*

Table of Contents

Key terms and acronyms used in this document

Commissioning: This is the process of obtaining and recording evidence that equipment has been supplied and installed in accordance with the specifications of the manufacturer; that it is safe to operate; and that it functions properly within the limits predetermined by the **Manufacturer's Instructions.**

Competent Person (Decontamination): This person is responsible for the validation of decontamination equipment and should have a qualification in this area such as a Test Person Certificate or other appropriate qualification.

Competent Person (Pressure Vessel): This person should carry out checks on Pressure Vessels such as Small Steam Sterilisers in accordance with the legal obligation imposed by S.I. 445 of 2012 and should be a suitably qualified engineer nominated by your insurance company.

Decontamination Lead: This person is the member of staff given responsibility for infection prevention and control, including decontamination and staff training. This person must have appropriate training and authority and will report to the Principal Dentist/Podiatrist or Practice Manager.

Features: Terms used by HIQA to describe the elements of a Standard that, when taken together, will enable progress towards achieving the Standard.

Healthcare Associated Infections (HCAI): Infections that are acquired after contact with a Healthcare Service.

Healthcare Professional: A person who exercises skill or judgement in diagnosing, treating or caring for patients and preserving or improving their health. For the purpose of this document, the term includes Health and Social Care Professionals as defined in the Health and Social Care Professionals Act 2005.

Infection: Invasion of the body by a harmful organism or infectious agent such as a virus, parasite or bacteria.

Infection Prevention and Control (IPC): The discipline and practice of preventing and controlling HCAIs, infectious diseases etc.

LDU: Local Decontamination Unit.

Patient: This refers to a person who uses the Primary Care Services.

Periodic Testing: This is a programme of testing that shows that the performance of an Ultrasonic Cleaner, Washer Disinfector and steriliser is consistently acceptable. The tests should be carried out once a day, once a week and once a year as is appropriate in each case.

RIMD: Reusable Invasive Medical Device.

Service Provider: This refers to any person, organisation or part of an organisation delivering Health and Social Care Services.

Staff: The people who work in Primary Care Service, including Dental, Podiatry, and GP services.

Standard: Describes the high-level outcome required to contribute to quality and safety of the service.

User: This is the person authorised to use decontamination equipment. This person must be suitably trained in the use of this equipment and also be able to carry out the daily and weekly tests required.

Validation: This is the process for obtaining, recording and interpreting the results needed to show that a process will consistently yield a product complying with predetermined specifications.

WD: Washer Disinfector.

1. Introduction

1.1 Prevention and control of Healthcare Associated Infection

The Health Information and Quality Authority (HIQA) has developed the National Standards for Safer, Better Care to describe what a high quality, safe service looks like. Improving the quality of care and providing a safe working environment are thus fundamental activities for the Health Service Executive. Prevention and control of Healthcare Associated Infection (HCAI) is central to these activities.

Senior managers must ensure that they have effective systems in place in their healthcare facilities to minimise the risks of infection to service users and staff. The Standards and Recommended Practices for Decontamination in a Primary Care LDU have been devised to support understanding of the legal and legislative requirements relating to decontamination of RIMD and promote a standardised approach to safe decontamination practice in Primary Care.

1.2 Decontamination process

Decontamination is the combination of processes (including cleaning, disinfection and sterilisation) used to render RIMD safe for handling by staff and for use on service users. Effective decontamination of RIMD is an essential component in the prevention of Healthcare Associated Infection.

Cleaning is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.

Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores.

Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. Sterility is an absolute condition, an item is either sterile or not sterile.

When describing a sterilisation process, it is impossible to say that the chance of an organism surviving a sterilisation process is zero. For medical equipment, it is acceptable to achieve a sterility assurance level of one in a million chances of a single organism surviving the process.

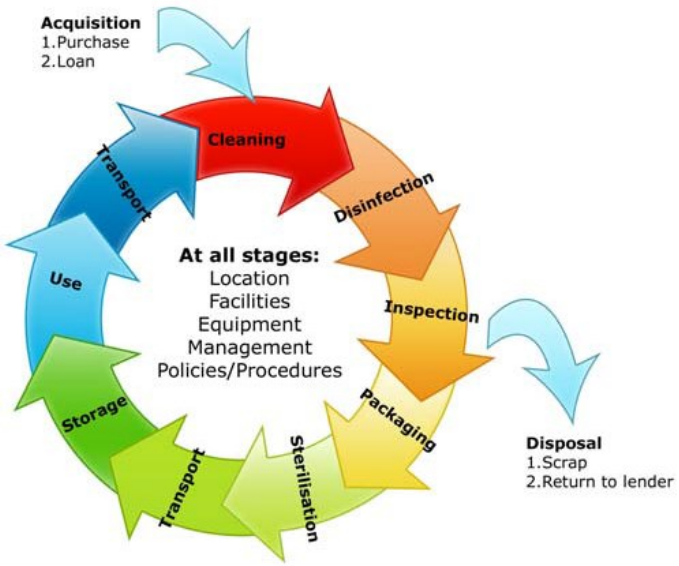
1.3 Effectiveness of decontamination

The effectiveness of the decontamination of RIMD used in the Primary Care setting is determined by all elements of the RIMD life cycle, which includes selection, specification, purchase, transport, storage and eventual disposal of RIMD and purchase, validation, maintenance and testing of associated decontamination equipment and processes. All aspects of the life cycle need to be controlled and managed if decontamination is to be fully effective.

This involves a multidisciplinary approach to the prevention and control of infection, including (in no particular order of priority):

- Standards, Policies, Procedures, Protocols and Guidelines in relation to decontamination.
- Maintaining a controlled environment.
- Investigation of incidents.
- Education and training of staff.
- Validation, maintenance and periodic testing of decontamination equipment.

Figure 1: Decontamination life cycle



2. Development of Standards and Recommended Practices for Decontamination of Reusable Invasive Medical Devices used in Primary Care

2.1 Introduction

The Standards and Recommended Practices for decontamination of RIMD in Primary Care were developed as follows:

- Extensive literature search.
- Regulatory and legislative requirements for decontamination of RIMD.
- Consideration of the opinion of experts knowledgeable in the subject.
- Consideration of the available current best practice, both in Ireland and internationally, that may impact on decontamination of RIMD
- Development of draft Standards and Recommended Practices for distribution to key stakeholders for consultation
- Feedback considered and where appropriate, incorporated into the current version of the Standards and Recommended Practices

Important Note: *Practices that use sterile Reusable Invasive Medical Devices must choose from the following 3 options:*

1. *Use sterile single use medical devices which will obviate the need for decontamination.*
2. *Have RIMD decontaminated and sterilised by a Central Decontamination Unit (CDU) , ensuring the Primary Care facility remains the owner of the RIMD . The Primary Care Facility must ensure there is a tracking system in place to track the devices through the decontamination process and link the devices to the patient on whom the devices are used. A Service Level Agreement must be in place detailing clear allocation of responsibilities and duties of both parties. Outsourcing the decontamination of RIMD does not obviate the need for the Primary Care Facility to provide assurances that the CDU operates in compliance with HSE , European and Regulatory Standards . In addition there is a legal obligation (when transferring contaminated medical devices) to comply with the S.I. No. 288 of 2015, "Carriage of Dangerous Goods by Road Regulation".*
3. *Decontaminate RIMD in the local LDU , the practitioner should comply with the recommendations set out in the following:*

- *Guidance for Application of Standards and Recommended Practices for Local Decontamination Unit's in Primary Care, Dental , Podiatry and GP Practice (2019).*

3. HIQA Standards for Safer Better Healthcare

The Health Information Quality Authority identify 8 themes for quality and safety which are intended to work together. Collectively, these themes describe how a service provides high quality, reliable safe care centered on the service user. The four themes on the upper half of the figure relate to dimensions of quality and safety, the four themes on the lower half of the figure relate to capacity and capability.

Decontamination practices in Primary Care are aligned to all 8 themes; however Effective Care and Support and Safe Care and Support are the key dimensions of quality and safety needed to support the delivery of safe decontamination services in a Primary Care Dental, Podiatry or GP LDU.

Figure 2: Themes for Quality and Safety

3.1 Definitions

Themes= The Health Information Quality Authority identify 8 themes for quality and safety which are intended to work together. Collectively, these themes describe how a service provides high quality, reliable safe care centered on the service user.

Standards = Term used by the Health Information Quality Authority and the Health Service Executive to describe the high-level outcomes required to contribute to the quality and safety of decontamination services.

Features = Term used by the Health Information Quality Authority to describe elements of a Standard that when taken together, will enable progress toward achieving the Standard.

Recommended Practices = Recommendations concern best practice in relation to the decontamination process.

The Recommended Practices are intended to define correct decontamination practice and to promote service user and staff safety. They are also intended to serve as the basis for policy and procedure development when decontaminating RIMD in Primary Care.

4. What do HIQA Standards mean for Decontamination Practice in Primary Care Dental, Podiatry and GP Services?

Theme 1: Patient Centred Care and Support	
Standard 1.1	Healthcare professionals effectively communicate with their patients about prevention, control and management of healthcare associated infection.

Theme 2: Effective Care and Support	
Standard 2.1	Decontamination and infection prevention and control practice reflects national and international evidence of what is known to achieve best outcomes for patients.

Theme 3: Safe Care and Support	
Standard 3.1.1	An effective risk management strategy is in place to protect and minimise potential Healthcare Associated Infection risks from the service to patients.
Standard 3.1.4	Systematic identification of aspects of the delivery of care associated with possible increased risk of harm to service users and structured arrangements to minimise these risks including management and use of Reusable Invasive Medical Devices and decontamination equipment.
Standard 3.1.6	Safe and effective management of medical devices in accordance with legislative requirements, national policy/guidelines and best national/ international evidence.

Theme 6: Workforce Planning	
Standard 6.3	Service providers ensure their workforce have the competencies to deliver high quality safe effective care.

What does this mean to the service user?

The service is always looking for ways to make your healthcare safer.

The service is not just reacting when things go wrong—it is actively looking for ways to make the way it provides care safer.

The service learns from international and national evidence about the best ways of keeping you safe.

The service uses information relevant to the provision of safe services to inform continuous improvement of the safety of the service.

Theme 1: Patient Centred Care and Support	
Standard 1.1	Healthcare professionals effectively communicate with their patients about prevention, control and management of healthcare associated infection.

Features of a service meeting this Standard and Recommended Practices include:

1.1.1 Clear communication with every patient and their relative/carer throughout the care pathway about the importance of the prevention, control and management of infection, including HCAIs.

1.1.2 Support and encouragement for patients and or relatives/carers to provide feedback, raise concerns or make complaints.

Theme 2: Effective Care and Support	
Standard 2.1	Decontamination and infection prevention and control practice reflects national and international evidence of what is known to achieve best outcomes for patients.

Features of a service meeting this Standard and Recommended Practices include:

2.1.1 All Reusable Invasive Medical Devices are safely and effectively decontaminated in keeping with Legislation, national recommendations, standards and quality improvement initiatives that are based on best available evidence.

2.1.2 Development of local policies, procedures and protocols is consistent with current national guidelines and adheres to an evidence-based process. These are updated at least every 2 years and upon publication of new guidance.

Theme 3: Safe Care and Support	
Standard 3.1.1	An effective risk management strategy is in place to protect and minimise potential Healthcare Associated Infection risks from the service to patients.

Features of a service meeting this Standard and Recommended Practices include:

3.1.1 Implementation of evidence based clinical practice guidance and relevant legislation by the service to identify and manage occupational risks for exposure to HCAIs and injuries*

- The Health and Safety Authority Guide to the European Union Regulations (2014) " Prevention of Sharps Injury in the Health Sector" recognises that personnel working in decontamination practice are at risk of sharps injury.
- Use of a Washer Disinfector will minimise handling of contaminated sharp instruments and thus risk of sharps injury.
- Staff are facilitated to comply with standard precautions in all healthcare settings, for all patients, whether infection is known to be present or not. Staff are aware of the correct indications for application of personal protective equipment, including requirements for exposure prone procedures.
- Staff are informed of the benefits and drawbacks of vaccination and failure to vaccinate. It is recommended that as a minimum that all staff who are at risk through contact with blood and/or body fluids should be immunised against Hepatitis B Virus (HBV), unless immunity has been previously established or vaccination contraindicated.

*Injury includes needle stick or other sharps injury from instruments, human bite, splash from blood and body fluids may be associated with manual cleaning practices (especially exposure to broken skin or mucous membranes)

- Waste management should be in line with the HSE/SARI Infection Prevention and Control for Primary Care in Ireland—A Guide for General Practice (2013). http://www.hpsc.ie/A-Z/MicrobiologyAntimicrobialResistance/ InfectionControlandHAI/Guidelines/File,14612,en.pdf

  Systemic identification of potential risk factors associated with staff acquiring a HCAI. These include but are not limited to:

  - Skin conditions such as dermatitis or other skin conditions that causes a break in skin integrity;
  - allergies to products such as latex and hand hygiene products
  - exposure prone procedures;
  - high risk settings such as decontamination
  - current infection and
  - vaccination refusal/non-responder.

- Sharps must be disposed of at the point of use, prior to the transport of devices to the LDU. Personal Protective Equipment is available to staff to avoid sharp accidents and/or exposure to blood or body fluids. A Washer Disinfector is used to minimise handling of contaminated instruments.
- Provision of training relating to the risk of sharps injury to decontamination staff who are exposed to these risks.
- Staff must report any accident or incident involving an exposure to the risk of injuries and/or infections from sharps.
- Assessment and management± of staff as soon as possible following any injury sustained during the course of work.
- Primary Care services should have arrangements in place for staff to access post-exposure prophylaxis if required.
- Regular monitoring on occupational related injury and HCAI rates to identify high risk healthcare settings. Quality improvement action involving the implementation of suitable control measures to achieve a safe work environment.

±Management includes first aid, risk assessment, testing, treatment (including post-exposure prophylaxis for HBV and HIV, where applicable), counseling and follow-up, records and documentation

Theme 3: Safe Care and Support	
Standard 3.1.4	Systematic identification of aspects of the delivery of care associated with possible increased risk of harm to service users and structured arrangements to minimise these risks including management and use of Reusable Invasive Medical Devices and decontamination equipment.

Features of a service meeting these standard and recommended practices include:

3.1.4 Decontamination is performed in a suitable location external to the clinical treatment area. This area facilitates the separation of clean and dirty activities.

When designing a new local decontamination unit for Primary Care services there must be dedicated non-clinical space provided for decontamination of RIMD, to minimise opportunities for cross-infection of service users, clinical staff and cross-contamination of the working environment.

Dividing the instrument decontamination area into two physically separate working areas (one for cleaning and disinfection and one for packaging and sterilisation) should be the normal practice when servicing larger clinics , however, this may not always be possible to achieve in smaller clinics.

For smaller clinics the separation of clean and dirty activities should be in accordance with a “traffic light” zoning systems to minimise the risk of cross contamination in smaller LDU’s.

Red Zone : The red zone is the area where RIMD, which have been used on a patient, are returned to the LDU for reprocessing. This is the most contaminated zone in the LDU.

Amber Zone: The amber zone is the area where RIMD are inspected, packaged and prepared for sterilisation.

Green Zone: The green zone is the area where medical devices are released for dispatch and storage after steam sterilisation prior to reuse on the patient.

Figure 3: Single room LDU with zoning

Ventilation and Air Quality

Ventilation and air quality are important considerations.

All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures are controlled between 18-22^{o}C and relative humidity is controlled within the range 35-60%).

In non-purpose-built facilities, the control of airflow is a challenging issue and the practice should consider how good standards can be achieved without resorting to unreasonably complex or expensive ventilation systems.

Through-wall fan-based ventilation and extraction units will often be useful in this context. In particular, cassette-based systems can be simple to install and produce a balanced airflow at low cost. The use of freestanding or ceiling-mounted fan units, however, is not recommended.

The ventilation system in the decontamination area or room(s) should be designed to supply reasonable quantities of fresh air to the positions where persons work and to remove excess heat from equipment and processes. Where used, mechanical extract units should be ceiling- or wall-mounted. Care should be taken to ensure that airflow is from clean to dirty.

Figure 4: Double room LDU with physical separation of clean and dirty area

Ventilation and Air Quality

Where full mechanical ventilation solutions are used, for larger two room facilities, the extract system should be located and sized to draw about one-third of the air across the decontamination benches in the clean-to-dirty direction. Practices are advised to consult a heating and ventilation engineer if choosing to install a mechanical ventilation system.

Additional Information

Detailed guidance can be found in Health Technical Memorandum 03-01: Specialised Ventilation for Healthcare Premises, Health Building Note 00-09 – Infection Control in the Built Environment and Health Building Note 11-01:Facilities for Primary and Community Care Services.

(***Note:*** *The Dublin Dental University Hospital devised a video of the work flow, processes and procedures for effective Decontamination of Reusable Invasive Medical Devices in Primary Care Dental, GP and Podiatry services (2016). Access is available on: http://www.hse.ie/eng/about/Who/qualityandpatientsafety/Medical-Devices/decontamination/*)

- Appropriate arrangements are in place to support safe effective use of decontamination equipment associated with the reprocessing of Reusable Invasive Medical Devices.
- All Reusable Invasive Medical Devices are CE approved.
- Single use devices are never reused.
- All equipment used to decontaminate medical devices is CE approved and conforms to relevant European Standards.
- Installation, commissioning servicing and annual revalidation of decontamination equipment is in compliance with European Standards and National Guidance and the Medical Device Regulation 2017/745 EEC.
- Examples include:

  - Washer Disinfector must conform to: EN 15883- Part 1, 2 and 5
  - Ultrasonic Cleaner must conform to: EN 15883-Part 1, 2 and 5
  - Small Steam Steriliser must conform to: EN 13060.
  - Decontamination of Reusable Invasive Medical Devices complies with manufacturer's instructions.

Figure 5: Do not reprocess symbol

Theme 3: Safe Care and Support	
Standard 3.1.6	Safe and effective management of medical devices in accordance with legislative requirements, national policy/guidelines and best national/ international evidence.

Features of a service meeting this Standard and Recommended Practices include:

Cleaning and Disinfection: The EU Sharps Directive (2014) recognises that staff working in decontamination facilities are at high risk of sharps injury. Manual washing is therefore only used when manufacturer's instructions specifically state that the device is to be cleaned by manual cleaning methods only.

Use of a Washer Disinfector will minimise handling of sharp contaminated medical devices. This will ensure that the risk of sharps injury to staff and risk of infection transmission is minimised.

RIMD must be compatible with the detergents and decontamination methods that are used.

*(**Note:** To ensure that devices with lumens and in particular dental hand pieces are effectively decontaminated; the Washer Disinfector must have the appropriate connections to allow flushing of detergent and water into the lumens of the hand pieces, please reference additional information in Appendix III)*

Standards: The Washer Disinfector must be compliant to EN15883.

The use of a Washer Disinfector will provide a validated, repeatable cleaning and disinfection method for medical devices. A datalogger/printer or network cable needs to be supplied to ensure each Washer Disinfector cycle is recorded, reviewed and signed off by the User prior to inspection and packaging.

Ultrasonic Cleaner: If a Washer Disinfector is currently unavailable, an Ultrasonic Cleaner may be used to pre clean RIMD. A datalogger/printer or network cable needs to be supplied to ensure each Ultrasonic Cleaner cycle is recorded, reviewed and signed off by the User. An Ultrasonic Cleaner will not disinfect medical devices and thus devices pre cleaned in an Ultrasonic Cleaner will still be contaminated and present a sharps injury risk to the User.

Sterilisation: There are 3 types of bench top Small Steam Sterilisers. Use of a Class B Small Steam Sterilisers is the **preferred** option as it is capable of sterilising all loads including bagged instruments, hinged instrument, lumens (e.g. dental hand pieces) and porous loads (IDC, 2015). All new Small Steam Steriliser purchases should be Class B type Small Steam Sterilisers.

(Note: Class N Small Steam Sterilisers should only be used for sterilising unwrapped solid instruments for immediate use. The devices may be sterilised, however the sterility at the point of use is not guaranteed as these devices are not wrapped. Instruments processed in Class N Small Steam Steriliser must not be subsequently wrapped and stored. Class N Small Steam Sterilisers are not suitable for lumen devices or porous loads. Class S Small Steam Sterilisers must only be used in accordance with manufacturer's specifications)

EN Standards: Small Steam Sterilisers must be compliant to EN 13060 and be supplied with a datalogger/printer or network cable to ensure each sterilisation cycle is recorded, reviewed and signed off prior to release of the load, ensuring all parameters of the cycle have been met.

Commissioning and Validation: At minimum decontamination equipment must be installed and commissioned by a Competent Person who provides documented evidence that they have been trained to commission and validate this equipment. Thereafter the Primary Care LDU will ensure that at minimum an annual validation and service of all decontamination equipment is performed by a Competent Person. All commissioning, servicing and re-validation and documents must be retained by the User for 11 years (current HSE Guidance) plus the lifetime of the equipment. Review documentation to ensure it is complaint to all relevant national and international standards.

There are occasions when a sterliser will need to be revalidated outside of the annual requirement. Changes to be considered (if applicable) shall include:

- Replacement of a process control part which could cause a process parameter to change (e.g. replacement of a drain probe or replacement of a Central Processing Unit card);
- replacement of a part which could cause an increase in leakage into the steriliser chamber;
- variation of homogeneity in the steriliser chamber;
- new or modified software and/or hardware;
- any change to a process parameter or
- any change of packaging and/or packaging procedure; load configuration.

Performance Monitoring: Daily, weekly testing is performed by the User on all decontamination equipment to ensure continuous performance of the equipment to specification.

Compliance with manufacturer's guidelines for decontamination of RIMD including instructions for disassembly and reassembly prior to cleaning.

Documentation: The documentation of the decontamination process includes a Track and Trace record of each part of the decontamination process, including batch labels for each set of instruments, signed decontamination cycle records/equipment printouts which are linked to the patient on whom the devices have been used and should be kept for a minimum of 11 years (current HSE Record Retention Policy , 2013) plus the lifetime of the decontamination equipment. Options to facilitate electronic recording of machine cycles and tracking all stages of the decontamination process should be considered when designing a new facility.

Users should ensure there are mechanisms in place to back up electronic records.

Monitoring of each decontamination cycle is required to ensure compliance with decontamination equipment standards and evidence-based best decontamination practice. Quality improvement action is taken to address non-compliance and to improve the service provided.

*(**Note:** The immediate removal of a Small Steam Steriliser from service is required if there is a cycle or test cycle failure, until documented engineer approval is provided that the Small Steam Steriliser is safe to return to service)*

Handling and Storage of Instruments after Sterilsation: It is very important that instrument packs are completely dry when stored as dampness encourages growth of microorganisms. Do not place newly sterilised Instruments packs on cool or solid surfaces as the heat from the instruments will cause condensation to form resulting in wet packs and possible microbial contamination. Careful handling and storage of sterilised wrapped instruments will ensure that the contents remain sterile until the pack is opened. Prior to use check the wrapping material for dampness, tears, broken seals or any other damage and that the label is intact and details are legible. Store wrapped instruments in clean enclosed cupboards to avoid damaging the outer protective wrapping. Do not store instrument packs on open shelving or work surfaces in clinical areas. Use first in first out stock rotation.

Theme 6: Workforce Planning	
Standard 6.3	Service Providers ensure their workforce have the competencies to deliver high quality safe effective care.

Features of a service meeting this Standard and Recommended Practices include:

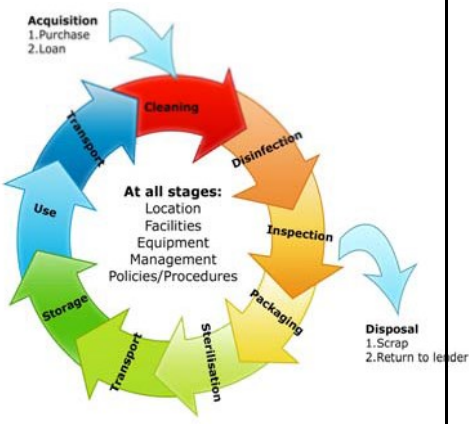
6.3.1 A formal mandatory induction programme for the workforce which includes a focus on communication and safety of users.

Staff involved in the decontamination of RIMD should be facilitated to maintain and develop their competencies to fulfill their roles and responsibilities in delivering high quality safe care.

Regular reviews of the development needs of the workforce is important , ensuring staff are supported to deliver high quality safe care. Action should be taken to address identified gaps in decontamination training.

Personnel who are involved in the decontamination of RIMD (User/Operator) must receive documented training from the Ultrasonic Cleaner, Washer Disinfector and Small Steam Steriliser supplier on the use of this equipment. In addition, the User/Operator must be trained by the supplier of this equipment, regarding the evidence that is needed to demonstrate that the load has been through an effective ultrasonic/wash/disinfection and sterilisation cycle.

Appendix I Self Assessment Tool (page 1 of 3)

IMB Safety Notice: SN2010(11) **HIQA National Standards for Safer Better Healthcare Standard 3.1.4, 3.1.6** **Medical Device Regulation 2017/745/EEC** **EU Directive Prevention of Sharps Injuries in the Healthcare Sector (2014)** **Irish Dental Council, Code of Practice relating to Infection Prevention and Control (2015)**		
Single use devices	**Essential**	**Single use devices are never reused**
Facility Design **There is enough space to facilitate adequate separation of clinical work and decontamination in the surgery.**	**Essential**	**Implement flow of instruments from 'dirty' zone to a 'clean' zone. Cleaning schedule in place.**
Follow the decontamination process 	**Essential**	**Implement following method of cleaning:** **(a) Use of a Washer Disinfector is essential to minimises handling of contaminated instruments and risk of sharps injury.** **(b) If Washer Disinfector is not currently available dirty instruments are directly placed in Ultrasonic Cleaner without manual cleaning (may be rinsed below the water in a sink).** ***(Note: that instruments are not disinfected after Ultrasonic Cleaning, presenting a sharps injury risk to staff)*** **(c) Instruments are inspected and packaged in a clean dry area away from the decontamination sink area and batch labeled for traceability.** **(d) Instruments are then placed in Small Steam Steriliser.**
Manual Cleaning • **Manually cleaning of Reusable Invasive Medical Devices is reserved for devices which, according to manufacturer instruction, cannot be processed in a Washer Disinfector.**	**Essential**	**(a) A dedicated sink is used to manually clean devices according to manufacturer instructions.** **(b) Manual cleaning is performed with equipment/ instruments fully immersed under the water surface (and not cleaned or rinsed under running water).** **(c) Detergent concentrations are compatible with the manufacturer's instructions and compatible with the device to be cleaned.** **Water temperature is below 45°C**
PPE • **Availability of good fitting heavy duty gloves, long handled brush and goggles/ visor and disposable apron and hand washing facilities.**	**Essential**	**(a) Manual cleaning of Reusable Invasive Medical Devices should not be performed routinely and only performed if the manufacturer instruction states that this is the only way to clean the de-vice.** **(b) In this instance -if instruments are to be manually cleaned or rinsed then good fitting heavy household gloves and a long armed brush, goggles/visor and disposable apron are required.**

Appendix I Self Assessment Tool (page 2 of 3)

IMB Safety Notice: SN2010(11) **HIQA National Standards for Safer Better Healthcare Standard 3.1.4, 3.1.6** **Medical Device Regulation 2017/745/EEC** **EU Directive Prevention of Sharps Injuries in the Healthcare Sector (2014)** **Irish Dental Council, Code of Practice relating to Infection Prevention and Control (2015)**		
Ultrasonic Cleaner • Ultrasonic Cleaner is CE marked. • Ultrasonic Cleaner is fitted with an inter- locking lid and fitted with a drain to allow ease of draining contaminated liquids. • New Ultrasonic Cleaners should be fitted with a printout. • Enzymatic Cleaner used. • A cleaning efficacy is tested weekly using a process challenge device . • Ultrasonic activity is checked regularly The Ultrasonic Cleaner has been commissioned and re validated at least annually to confirm functionality using the standards EN 15883.	**Essential** (if no Washer Disinfector is available at present)	The Ultrasonic Cleaning cycle should not be less than 5 minutes. (a) Always use the cleaning solution according to manufacturer's instructions and an enzymatic cleaner should be used. (b) Cleaning solution is changed at least every 4 hours or more frequently if visibly contaminated. *(Note: Instruments are not disinfected after Ultrasonic Cleaning therefore in the absence of a Washer Disinfector a sharps injury risk assessment is required)*
Washer/Disinfector • Daily checks for detergent, printer functionality etc. • Weekly cleaning efficacy test by residual soil detection . • Log of Washer Disinfector cycles. Installation and Commissioning document and at least annual revalidation to confirm functionality using the standard EN 15883.	**Best Practice - requires the installation of a Washer Disinfector.**	(a) Printer/USB or Network cable to record the decontamination process - sign off by User after each cycle. (b) Log book to be kept of wash cycles pass or fail. (c) Appropriate chemical storage is provided. (d) The Washer Disinfector has been commissioned to EN 15883, is subject to a planned preventative maintenance program and annual re-validation. (e) Daily and weekly tests are performed by the User.
Packaging	**Essential**	(a) Ensure that any instruments that are to be stored are wrapped before sterilisation using the correct programme on the Small Steam Steriliser. (b) Packaging should include a chemical indicator that is either printed on the pouch or available as a label or tape.
Vacuum Small Steam Sterilisers • Type and model. • Present with CE mark. • In use. Type B steriliser is required. Sterilisation at 134 ˚C - 137˚C for 3 minutes holding time -unless otherwise stated by the instrument manufacturer.	**Essential**	(a) Note Small Steam Steriliser type/class and make/ model number. Procedures must be in place to manage the use of equipment. (b) Printer/USB or Network cable to record the sterilisation cycle and a copy of each cycle is signed off by the User prior to batch release. (c) Procedures must be in place to ensure that when a test cycle fails that the Small Steam Steriliser is removed from service until an engineer is contacted and deems the Small Steam Steriliser fit for use.

IMB Safety Notice: SN2010(11) HIQA National Standards for Safer Better Healthcare Standard 3.1.4, 3.1.6 Medical Device Regulation 2017/745/EEC EU Directive Prevention of Sharps Injuries in the Healthcare Sector (2014) Irish Dental Council, Code of Practice relating to Infection Prevention and Control (2015)		
Monitoring of the Sterilisation Process requires tests or checks to be carried out: > On each Small Steam Steriliser Cycle. > Daily A warm up cycle with only Small Steam Steriliser chamber equipment present and a Helix Test or Bowie Dick Test. > Weekly Vacuum Test. Evidence of an Installation and Commissioning document and at least annual revalidation and preventative maintenance. *(Note: A laminated visual reference of all parameters and graphs for each cycle type must be provided by the steriliser manufacturer and displayed as a reference for staff in the LDU)*	Essential	(a) Test strips or colour indicator bags should be used with each cycle. (b) Daily and weekly monitoring tests must be undertaken on the Small Steam Steriliser using Helix Test or Bowie Dick Test daily and a Vacuum Test weekly. *(Note 1: Manufacturer's of Small Steam Sterilisers will indicate if a warm up cycle is needed prior to running daily tests)* *(Note 2: Manufacturer's will specify a specific cycle to be used for the Steam Penetration Test e.g. a Bowie Dick cycle. This cycle may have a reduced drying time and/or specific sterilisation holding time)* *(Note 3: Manufacturer's of the Small Steam Steriliser will specify whether it is a Helix Test or Bowie Dick Test that is needed daily)* The steriliser has been commissioned to EN 13060, is subject to a planned preventative maintenance program and annual re-validation.
• A log of Small Steam Steriliser test cycles is kept.	Essential	A log book to be kept if test cycles pass or fail and each sterilisation cycle, including evidence that the Helix or Bowie Dick test and vacuum tests have been completed. Test strips should be attached to the log book along with batch labels for each cycle and signed print outs which record date, time, temperature, pressure and holding times achieved. All values must be within the range for the cycle and are comparable to the values obtained at validation. All sterilisation cycles to be checked and signed before product release.
Storage of Instruments – • Are instruments stored appropriately to avoid recontamination? • Are stored instruments dated? • Are instruments rotated? • Is there an instrument tracking system?	Essential	(a) Any sterilised instruments stored must be wrapped/bagged and placed in a clean dry secure location away from sunlight. (b) Ensure that any instruments that are sterilised for storage have the sterilsation date and the Small Steam Steriliser cycle attached to the packaging. (c) Stored instruments should be rotated. (d) An Instrument Tracking System should be in place. Tracking involves recording the date and batch number of the sterilisation cycle and linking it to the patient on whom the device has been used.

Appendix II Equipment Testing Protocols

Table 1: Testing Washer Disinfectors

Minimum testing required for safe use of a Washer Disinfector in Primary Care
Daily checks (User)
1. Check spray arm rotation for free movement and remove and clean strainers and filters etc.
2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages for instruments)
Weekly tests (User)
1. Carry out daily checks
2. Cleaning efficacy test by residual soil detection
3. Process challenge device such as a "load check indicator"
Yearly and revalidation tests (Competent Person)
1. Yearly safety checks
2. Automatic control test
3. Verification of calibration of WD instruments
4. Chemical additive dosing tests for reproducibility and low level detection
5. Cleaning efficacy test
6. Thermometric test for thermal disinfection

*(**Note**: This is the minimum set of tests required to establish continued performance of the Washer Disinfector to specification). Validation of decontamination reprocessing equipment must be independently measured using dataloggers equipment that has been calibrated and measured to source documents)*

Table 2. Automated Washer Disinfector temperature band

A0 value	Temperature	Holding Time (Seconds)	Holding Time (Minutes)
600	90°C	60	1

Table 3. Testing Ultrasonic Cleaner

Test for Ultrasonic Cleaner
Daily checks (user)
1. Remove and clean strainers and filters etc.
Weekly tests (user)
1. Carry out daily checks and test for cleaning efficacy using a process challenge device such as a "load check indicator "
Quarterly Test (user)
1. Carry out daily and weekly checks 2. Test for ultrasonic activity using sono check or similar
Yearly and revalidation tests—(Competent Person)
1. Yearly safety checks
2. Automatic control tests (if an automatic cycle control is fitted)
3. Cleaning efficacy test
4. Test for ultrasonic activity

Table 4. Testing of Sterilisers

Sterilisation temperature, steam pressure and hold time

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximum Permissible Temperature	Minimum Sterilisation Hold time
134°C	2.30 bar gauge	137°C	3 minutes

Performance qualification

3.1 Performance qualification is required to show that sterilising conditions are attained for typical loads and also test loads that are difficult to sterilise. Performance qualification is indicated for initial use of a new steriliser or when the load profile changes (e.g. new types of RIMD or packaging). It should be carried out by a Test Person or suitably qualified person (decontamination).

Performance qualification tests consist of:

a. Air leakage tests (automatic).

b. Thermometric tests of all dental RIMD to be processed.

c. Steam penetration test (e.g. Bowie and Dick).

d. Load dryness test (required for sterilisers with drying cycles).

3.2 The performance qualification test protocol and data should be audited by the qualified person (decontamination).

Periodic testing

3.3 Periodic testing consists of a programme of tests that are intended to show that the steriliser's performance is continually satisfactory. The appropriate tests should be carried out at daily, weekly and annual intervals. It is the responsibility of the Practice Manager to ensure that these tests are performed.

3.4 After appropriate training the user should perform the daily tests. Many modern sterilisers have an integrated automated test facility that enables the steriliser to perform some of the specialised weekly tests itself. These can be undertaken by the User after appropriate training. Annual tests should be performed by a Test Person or suitably qualified person (decontamination). Each cycle available to the User should be tested. If the steriliser is not tested periodically it will not be possible to know if it is working correctly. Failure of a test implies that the steriliser is not working to specification.

3.5 The User should have a written procedure for handling test failures but, in all cases, the steriliser must be withdrawn from service, the failure investigated, the cause rectified, and the steriliser re-tested successfully before being used. The User has the ultimate responsibility for certifying that the steriliser is fit for use.

Daily Testing

Daily Test—Bowie and Dick/Helix

3.6 These tests are intended to show that steam will penetrate rapidly and evenly into a test device as outlined in the manufacturer's instructions. The test device contains an indicator that sits inside a Process Challenge Device, (PCD) that responds (usually it changes colour and should do so completely) only when steam penetration is adequate. If a cycle is provided specifically to test the effectiveness of steam penetration, it should have the same air removal stage as used during routine sterilisation cycles. A Bowie and Dick Test pack is an example of a Process Challenge Device as is a Helix. The PCD is used solely to demonstrate a basic level of steam penetration, the manufacturer will also need to specify if a "warm up cycle" is required prior to performing daily tests.

The manufacturer of your steriliser will recommend which Helix Test or Bowie Dick Test you should use. You may note a shorter drying time for these tests. The holding time will be set by the manufacturer of the Steam Steriliser in compliance with the intended performance of the Process Challenge Device .

Test procedure

3.7 A standard test device should be placed in an otherwise empty chamber, in the position specified by the manufacturer.

3.8 At the end of the process the test device is removed from the chamber.

3.9 The test device is checked for a pass or fail in accordance with the manufacturer's instructions/recommendations. The test results should be recorded.

3.10 If the test fails, the test should be repeated. If the repeat test fails, contact the appropriate personnel and record results.

3.11 The sterilisation temperature for the operating cycle to be tested should be selected this should be the highest temperature compatible with the load. The cycle should be commenced.

3.12 A batch (cycle) process record should be made in the steriliser log book.

Table 5. Weekly and Annual Testing of Small Steam Sterilisers

Weekly Checks/Tests	**Type N Small Steam Steriliser**	**Type B and S Small Steam Steriliser**
1. Air leakage test	N.A.	Yes
2. Automatic air detection system function test (if fitted)	N.A.	Yes
3. Automatic control test	Yes.	Yes
4. Steam penetration test	Yes	Yes
Annual Tests for Sterilisers	**Type N Small Steam Steriliser**	**Type B or S Small Steam Steriliser**
1. Air leakage test (automatic)	N.A	Yes
2. Air leakage test (manual) (temperature and pressure sensors	N.A	Yes
3. Automatic control test	Yes	Yes
4. Verification of calibration of steriliser instruments	Yes	Yes
5. Thermometric test for a full load	Yes	Yes
6. Porous load dryness test	N.A	Yes
7. Test for performance re-qualification as required by the user	Yes	Yes
8. Air leakage test (automatic) (sensors removed)	N.A	Yes
9. Steam penetration test	N.A	Yes

Annual Testing

3.13 Annual testing and servicing is performed by a qualified engineer (table 5).

*(**Note:** Validation of decontamination reprocessing equipment must be independently measured using dataloggers equipment that has been calibrated and measured to source documents)*

Weekly Testing

Weekly Safety Checks

3.14 These tests are intended to ensure the steriliser is both safe to use and to test.

They consist of:

- Examining the door seal for signs of deterioration or leaks.
- Checking the security and performance of door safety devices.
  No attempt should be made to open the door while the chamber is pressurised.

Any defects should be corrected before attempting to perform the weekly tests or before using the steriliser.

Vacuum Leak Test

3.15 The air leakage test is intended to check that air does not leak into the steriliser during periods of vacuum, at a rate that is greater than that specified by the steriliser manufacturer.

Air leaking into the chamber can impair steam penetration into the load and prevent sterilisation and/or recontaminate the damp load during the drying phase.

Air is first removed from the chamber until the pressure is the lowest achieved in all of the cycles available on the steriliser and then the vacuum source is isolated and all valves connected to the chamber are closed.

The absolute pressure is measured at the end of the vacuum stage. Any subsequent rise in the chamber pressure will be caused by air leaking into the chamber with the rate of pressure rise in the chamber measured.

The pass/fail criteria are:

The absolute pressure at the end of the air removal stage should be within the limits specified by the manufacturer. After an initial 5 minute equilibration period the rate of pressure rise should not be greater than 1.3 mbar per minute over a 10 minute period.

A machine that fails to meet the requirements of this test should not be used until the fault has been rectified and the test satisfactorily completed.

Appendix III Guidance for Procurement of Decontamination Equipment and RIMD

Purchasing Reusable Invasive Medical Devices (RIMD)

Before buying instruments: Always purchase from a reputable supplier.

Check the manufacturer's decontamination instructions to ensure that the instruments can be decontaminated with the equipment and facilities that you have available, or buy single-use instruments.

Instruments should be capable of being cleaned, disinfected and sterilised using an automated validated process.

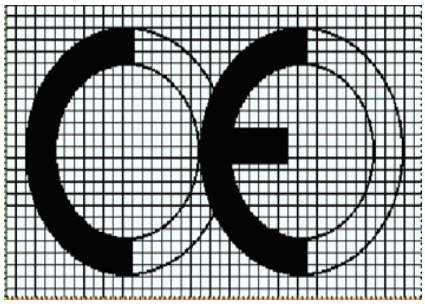
Some RIMD possess internal lumens, for example, dental hand pieces. Users should always aim to purchase instruments such as dental hand pieces that can be processed in a Washer Disinfector and sterilised in a Small Steam Steriliser. Specific attachments for the Washer Disinfector which allow the lumens to be irrigated must be purchased . Dismantling instructions must be provided to ensure that the internal mechanisms of the device are appropriately cleaned, disinfected and sterilised. The manufacturer will need to provide training to decontamination personnel on how the devices should be decontaminated.

All medical devices purchased for use in Primary Care Practice must be CE marked.

CE stands for: European Conformity. The CE mark is not a mark indicating conformity to a Standard but rather a mark indicating conformity to the legal requirements of European Union (EU) Directives. When a product has the CE mark, it can be traded freely in any country within the European economic area.

Before the CE mark can be placed on the label or packaging of a RIMD, the RIMD must conform to the requirements of the legislation. The CE marking of conformity must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use.

Figure 6: CE Symbol



Purchasing a Washer-Disinfector

Always purchase from a reputable supplier.

WDs are used to carry out the processes of cleaning and disinfection consecutively. Using a WD requires several resources, including:

- Appropriate staff training in operating the WD (e.g. on installation);
- adequate space and provision of utilities (drainage, water, electricity);
- compatible instruments and tray systems and
- a sufficient quantity of instruments.

Obtain recommendations from the WD manufacturer for the most efficient design and size of trays for use in your Washer-Disinfector and Small Steam Steriliser.

- Instruments must be loaded correctly to ensure adequate cleaning. This will be determined at installation and validation.

A typical WD cycle for instruments includes the following five stages:

Flush – Removes 'difficult' gross contamination, including blood, tissue debris, bone fragments and other fluid and solid debris. Latest standards indicate that a water temperature of <45°C is used to prevent protein coagulation and fixing of soil to the instrument.

Wash – Removes any remaining soil. Mechanical and chemical processes loosen and break up contamination adhering to the instrument surface. Detergents used in this process must be specified by the manufacturer as suitable for use in a WD.

Rinse – Removes detergent used during the cleaning process. This stage can contain several substages.

Thermal disinfection – The temperature of the load is raised and held at the pre-set disinfection temperature for the required disinfection holding time, e.g. 90˚C for 1 minute.

Drying – Purges the load and chamber with heated air to remove residual moisture. The cycle time depends on the model of the WD.

It is essential that each WD is CE marked correctly installed, validated, operated, maintained and regularly tested to ensure it is safe, is cleaning Primary Care instruments effectively and to protect your rights should any clinical or decontamination equipment failures occur.

Install and validate each Washer Disinfector in accordance with EN 15883. Ensure periodic testing, maintenance and operation of each Washer Disinfector is in accordance with the manufacturer's instructions.

Ensure staff are trained in the operation of the Washer Disinfectors, including daily and weekly testing. Keep records of all of these activities.

Different models of WDs are available that vary in size, design and capacity. Pass-through models have doors on two sides, which can facilitate the dirty-to-clean work-flow between the wash room and the sterilisation room in a two room LDU.

Figure 7: Primary Care Washer Disinfector

Ensure staff are given appropriate training by the supplier to operate the machine and record all activities. A datalogger or network cable must be provided to ensure records of the decontamination process are reviewed, parameters are met, signed off by the User prior to the release of the load and retained after each cycle. Mechanisms must be in place to ensure that electronic records are backed up regularly.

The Washer Disinfector manufacturer will recommend the type of water to be used. Preferably, use the same quality of water for rinsing instruments as is used for sterilisation. At each stage of the cleaning process the water quality should be compatible with:

- The components of the washer and steriliser;
- the RIMD to be processed and
- the process chemical to be used.

Purchasing an Ultrasonic Cleaner.

We have an Ultrasonic Cleaner why do we need a Washer-Disinfector?

An Ultrasonic Cleaner can be useful, although not essential, for removal of debris prior to processing in a WD, particularly for instruments with hinges and/or intricate parts.

(***Note:-*** *An Ultrasonic Cleaner will not disinfect your RIMD, therefore the instruments are still considered contaminated when removed from the Ultrasonic Cleaner*)

Ultrasonic Cleaning may also be used as a backup automated cleaning process in the event of WD failure. It is essential that Ultrasonic Cleaners are shown to be effective through regular testing and maintenance.

What do we need to know before purchasing an Ultrasonic Cleaner?

Purchase from a reputable supplier.

Before purchasing an Ultrasonic Cleaner ensure that the Ultrasonic Cleaner complies with the requirements EN 15883 and has the following features:

- CE marked;
- control of process variables such as time and temperature;
- a lid with an interlock to prevent operation of the cleaner when the lid is open (Ultrasonic Cleaners must be operated with the lid closed);
- a choice of load carrier(s) appropriate to the nature of the devices to be processed;
- a chamber drain-tap to enable the chamber to be emptied and
- a printer, datalogger or network cable should be provided to ensure records of the decontamination process are reviewed, signed off by the User and retained after each cycle prior to release of the load.

Purchasing a Small Steam Steriliser

To kill microorganisms, the instruments need to be exposed to steam at a specified temperature for a specific holding time. Although other options exist, the preferred temperature-pressure-time relationship for all Small Steam Sterilisers is 134–137°C, 2.1–2.25 bar gauge pressure for at least a 3 minute holding time. The sterilisation process must be validated to ensure that instruments are reliably and consistently sterilised using predetermined and reproducible conditions.

Purchase:

When purchasing your Small Steam Steriliser you should ensure that you purchase from a reputable supplier.

- The Small Steam Steriliser should be CE marked as this indicates that the manufacturer claims compliance with the Essential Requirements of the Medical Device Directive 93/42/EEC.
- There are 3 types of bench top Small Steam Sterilisers. Use of a Class B Small Steam Sterilisers is the **preferred** option as it is capable of sterilising all loads including bagged instruments, hinged instrument, lumens (e.g. dental hand pieces) and porous loads (IDC, 2015). All new Small Steam Steriliser purchases should be Class B type Small Steam Sterilisers.

  *(**Note:** Class N Small Steam Sterilisers should only be used for sterilising unwrapped solid instruments for immediate use. The devices may be sterilised , however the sterility at the point of use is not guaranteed as these devices are not wrapped. Instruments processed in Class N Small Steam Steriliser must not be subsequently wrapped and stored. Class N Small Steam Sterilisers are not suitable for lumen devices or porous load. Class S Small Steam Sterilisers must only be used in accordance with manufacturer's specifications)*
- Ensure the Small Steam Steriliser complies with EN 13060.
- Check with the supplier that they can commission, maintain and revalidate the steriliser to meet with HSE Standards and Recommended Practices for Decontamination of RIMD in Primary Care and EN 13060 standards and provide certification of Engineer/Test Persons Training.
- They must provide written operating instructions and training to decontamination personnel.
- They can guarantee an efficient repair service and response time and can provide replacement equipment if necessary.

- They can supply a contract for maintenance and testing in accordance with the manufacturer's instructions.
- The Small Steam Steriliser must be supplied with a datalogger/printer or network cable to ensure each sterilisation cycle is recorded, reviewed and signed off prior to release of the load, ensuring all parameters of the cycle have been met. Mechanisms must be in place to ensure electronic records are backed up regularly.

Specify clearly to the supplier the type of loads that you intend to reprocess including:

- The quantities of instruments you are likely to reprocess per load and per day;
- instrument cassette/tray dimensions (if used);
- whether the loads include solid or hollow instruments;
- how many instrument trays, cassettes or racks the steriliser can process in one cycle;
- how long a cycle takes;
- the number of different cycles the steriliser can perform;
- dimensions and door orientation;
- a local servicing agent;
- the costs involved for installation, validation, periodic testing and maintenance;
- periodic tests, including whether the machine can perform these tests automatically and whether the User can perform them;
- how long the machine is out of action for maintenance;
- the electrical and/or plumbing requirements;
- any other specific requirements (e.g. water quality and quantity required per cycle);
- whether the machine has a printer installed or an electronic datalogger and if so whether this records temperature, pressure and sterilisation hold time and
- whether other attachments or accessories are required and whether they have been included in the costs.

*(**Note:** Water used for sterilisation must be essentially free of chemicals and endotoxins. The use of tap water is not acceptable as this can lead to contamination of the medical devices and thus harmful to the patient and it may also damage the steriliser. The steriliser reservoir should be filled with water of a suitable quality, the water should be changed at least once a day or sooner if the chamber water is visibly cloudy or coloured. Record when the water change has taken place. If there is remaining water in the reservoir at the end of the day it must be removed)*

Resource

Department of Health NHS, Health Building Note 00-09: Infection Control in the built environment (2013) (https://www.gov.uk/government/uploads/system/uploads/ attachment_data/file/170705/HBN_00-09_infection_control.pdf)

Department of Health NHS, Health Building Note 11-01: Facilities for primary care and community care services (2013) (https://www.gov.uk/government/publications/guidance-for-facilities-for-providing-primary-and-community-care-services)

Department of Health NHS, Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises (2007) (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144029/HTM_03-01_Part_A.pdf)

European Directive on Medical Devices 93/42/EEC (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31993L0042)

European Standard for Small Steam Sterilisers EN 13060: 2014

European Standards for Washer Disinfectors and Ultrasonic Cleaner EN 15883: Part 1 :2014 and Part 2:2013

Guide to the European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations, 2014, HSA, 2014.(http://www.hsa.ie/eng/Publications_and_Forms/Publications/Healthcare_Sector/Sharps_Regulations_Guidelines_2014.pdf)

Health Information Quality Authority National Standards for Prevention and Control of Healthcare Associated Infection (2009)

Health Information Quality Authority National Standards for Safer Better Health (2012)

H. Lemass, N. McDonnell, N. O'Connor and S. Rochford, Infection Prevention and Control for Primary Care in Ireland – a Guide for General Practice, SARI 2013.

Health Service Executive Standards and Recommended Practices for Decontamination of Reusable Invasive Medical Devices in Primary Care (2016).

Infection Prevention and Control for Primary Care in Ireland – a Guide for General Practice, SARI, 2014.

Irish Dental Council, Code of Practice relating to Infection Prevention and Control (2015)

Scottish Dental Clinical Effectiveness Programme (2011), Sterilization of Dental Instruments, - Dental Clinical Guidance

Scottish Dental Clinical Effectiveness Programme (2014), Cleaning of Dental Instruments, 2nd edition Dental Clinical Guidance

S.I. No. 146 of 1994 and S.I. No. 248 of 1998, Safety, Health and Welfare at Work (Biological Agents) Regulations. (http://www.irishstatutebook.ie/1994/en/si/0146.html#zzsi146y1994a6) (http://www.irishstatutebook.ie/1998/en/si/0248.html)

S.I. No. 288 of 2015 Carriage of Dangerous Goods by Road Regulation (2015) (http://www.hsa.ie/eng/Legislation/Acts/European_Communities_Act/S_I_288_of_2015.pdf)

S.I. No. 445 of 2012, Safety, Health and Welfare at Work (General Application) (Amendment) Regulations, 2012. (http://www.irishstatutebook.ie/pdf/2012/en.si.2012.0445.pdf)

S.I. No. 135 of 2014, European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations, 2014. (www.hsa.ie/eng/Legislation/New_Legislation/S_I_135_of_2014.pdf)

Welsh Health Technical Memorandum (WHTM) 01-05 , NHS, (2014). (http://www.wales.nhs.uk/sites3/Documents/254/WHTM%2001-05%20Revision%201.pdf)