SESLHD PROCEDURE COVER SHEET

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KEY TERMS	Reusable Medical Device (RMD), Product Family, Instruction for Use (IFU)
SUMMARY	Assigning an RMD to a particular product family is the first stage of performance qualification at the point of use. Product Families are identified based on consideration of the product attributes which relate to efficient process. The objective of this procedure is to provide guidance about the attributes and assigning RMDs to a product family using those attributes.

Sterilisation: Designation of Reusable Medical Devices (RMDs) to a Product Family

SESLHDPR/627

1. POLICY STATEMENT

This procedure provides guidance about the attributes of RMDs to be considered by the Reprocessing Facility when assigning RMDs to a product family for the purpose of identifying and aligning it to a processing category for a specific cleaning, assembling, packaging and sterilisation processes.

2. BACKGROUND

The Manufacturer of a RMD will usually specify the attributes needed by the Reprocessing Facility to assign an RMD to a cleaning, assembling, packaging and sterilisation process.

The Reprocessing Facility shall ensure that the IFU of the RMDs presented for disinfection or sterilisation is controlled and shall not compromise the effectiveness of the process.

Product Family-Groups or subgroups of product characterised by similar attributes such as mass, material, construction, shapes, lumens, SBS, or packaging system and which present a similar challenge to the cleaning, disinfecting and/or sterilising processes.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure
- Report non-compliance with this procedure.

3.2 Sterilising Service Managers will:

- Implement the requirements of this procedure

4. PROCEDURE

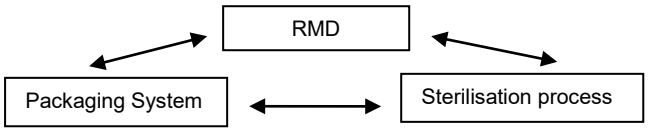
4.1 Assigning RMDs to a cleaning process

Reprocessing Facility will assign RMDs to a cleaning process that has been validated as per the general attributes below and as per Manufacturer's validated automated or manual cleaning method:

Design
Weight
Material

4.2 Assigning RMDs to a assembling and packaging system

Reprocessing Facility will assemble RMDs into sets which have been validated to a compatible sterilisation process.
The specific nature of the RMD, the intended sterilisation method, the intended use, the transport and storage all influence the choice of appropriate packaging system.



Interrelationships influencing the choice of packaging system

4.3 Assigning RMDs to a sterilisation process

Reprocessing Facility will assign RMDs to a sterilisation process that has been validated as per the general attributes below:

Design
Weight
Material
Sterile barrier system

The sterilisation process assigned to each product Family is first based on the design of the RMDs in the family and then adjusted if influenced by the other attributes.
The product family assigned to the RMDs compiled into sets will be determined by the RMD that has been identified as the greatest challenge to the sterilisation process.

5. DOCUMENTATION

Manufacturer's IFUs, Work Place Instructions

6. AUDIT

Reusable Medical Devices (RMD) Manual Cleaning-Audit
Reusable Medical Devices (RMD) Mechanical Cleaning-Audit
Reusable Medical Devices (RMD) Packing and Sterilising-Audit

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of Reusable Medical Devices in Health Service Organisations
- ISO 17664:2017 Processing of Health Care Products-Information to be Provided by the Medical Device Manufacturer for the Processing of Medical Devices
- ISO 17665-3:2013 Sterilisation of Health Care Products-Moist Heat
  Part 3: Guidance on the Designation of a Medical Device to a Product Family and Processing Category for Steam Sterilisation
- ISO 11607-2:2006 Packaging for terminally sterilised medical devices
  Part 2: Validation requirements for forming, sealing and assembly processes

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
25/07/2018	DRAFT	SESLHD Sterilising Services Working Group (SSWG)
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