Instructions For Use for reusable and re-sterilisable Medical Devices

1. Introduction

The mission of the Compliance and Enforcement Group (COEN) is to provide for the exchange of information between Competent Authorities (CA) responsible for market surveillance (MS) of medical devices (MD) and to coordinate their enforcement activities.

Following a number of individual actions of CA that revealed major non-conformities related to the instructions for use (IFU) of resterilisable medical devices (RMD) the COEN created the "IFU Working Group" to address this issue.

A harmonised standard exists for the sterilisation of medical devices to facilitate manufacturers in their compliance with section 13 of the essential requirements as set in Annex I of the medical device directive 93/42/EEC (MDD) namely EN ISO 17664 *"Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilisable medical devices"*. However it became clear in the course of the project that those involved in this particular sector urgently needed user-friendly guidance to allow them to assess safety and fitness for the purpose of RMD in addition to the harmonised standard. Consequently the present document is intended for all individuals and organisations involved in this sector, but more specifically targeting manufacturers, end users and procurement officers.

COEN encourages everyone having used any of these checklists to make suggestions in order to improve its value. Positive feedback is desirable too so that every aspect which has proved beneficial is left unchanged. Suggestions can be sent to **medical.devices@swissmedic.ch**

2. Checklist "Instructions For Use (IFU)"

2.1 Introduction

User reports and market surveillance activities have shown that a vast number of RMD are marketed without IFU. Two factors explain this situation.

First - Invasive surgical instruments may fall into class I (following rule 6 of Annex IX of the MDD) with the consequence that no third party is assessing the conformity that could force the manufacturer to supply IFU.

S*econd* -Even in case they fall into the class IIa (following rule 2), a provision of Annex 1 Section 13.1 allows to omit IFU "***if*** *they can be used* ***safely*** *without any such instructions.*". Experience shows however that manufacturers of RMD make frequent and unjustified use of this exception thus eluding both obligations first to supply detailed information on reprocessing and second to validate the procedure.

Indeed RMD have often geometrical or physical properties that may render the reprocessing difficult or questionable. Annex I Section 13.6 h of the MDD stipulates that *"...**if** the device is **reusable**..." the information for use (IFU) **must** provide,"... information on the appropriate processes to allow reuse, **including cleaning, disinfection**, packaging and, where appropriate, the **method of sterilization** of the device to be resterilized ...*".
Compliance with section 13.6 h can be assessed using the EN ISO 17664 standard. In reality, most users or purchasing officers are reluctant to use a twenty- plus pages document to make sure that the RMD is safe and fit for purpose. So they mostly rely on the presence of a CE marking to base their decision to use or purchase a RMD. As mentioned previously the compliance of class I devices is merely backed by a self-declaration of the manufacturer.

In Appendix 1 of this document, there is a checklist entitled "Checklist Instructions for Use (IFU)" that was originally intended for use by CA to review IFU of RMD conformity purposes. Although it closely follows EN ISO 17664, only checkpoints deemed most relevant for a quick assessment have been included. Therefore it is **not to be used** as substitute for the full EN ISO 17664 standard. Nevertheless, the checklist provides a quick and reliable way to assess IFU in view of making an informed decision on using or purchasing a specific RMD.

The underlying idea for publishing the checklist is to encourage improvements by those involved with selling within this sector by helping end users to feedback their findings to the manufacturers and CA. Thank to the checklist, particularly in the context of tenders, buyer-side actors are placed in a favourable position to successfully impose quick corrections. Secondly, the publication should raise awareness of regulatory matters relating to RMD and make known the expectations of CA among those involved with selling in this sector.

2.2 Using the Checklist IFU

The following explains how the checklist should be used to greatest effect. For each item to be completed, there are four possible answers based on the review of the IFU: "yes", "Not completely fulfilled (N.c)","Not fulfilled (No)" and "Not applicable (N.a)" (a rationale for "N.a" should be provided for all such answers). After having proceeded through the whole list, a review of the answers will give a good picture of what is missing and to what extent. Based on this quick check, every market actor can act according to its role. It must be stressed however that Manufacturers should continue to use the full EN ISO 17664 standard to demonstrate full compliance.

3. Checklist "Assessment of the Validation"

3.1 Introduction

We have seen in section 2.1 that to demonstrate compliance with the essential requirements manufactures can invoke the harmonised standard EN ISO 17664. This standard requires that information on at least one **validated procedure** has to be provided to the user.

At the same time, in order to avoid infection or cross-contamination it is vital for the patient's safety that whenever MD are to be used sterile they actually are sterile. Reprocessing RMD can be technically difficult and in some cases even impossible. Therefore it is necessary to validate the reprocessing procedure.

But what does validation actually mean? According to the standard EN ISO 14937, it is a *"**documented** procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications"*

How do you assess the validation of the reprocessing procedure? This is where the *"Checklist for the assessment of the validation of the reprocessing of reusable medical devices based on EN ISO 14937*", or "*Checklist Assessment of Validation*" for short comes into play.

It is mainly but not uniquely based on the harmonised standard EN ISO 14937 *"Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices "*. It

can only be used in conjunction with **actual data obtained from the validation** and was therefore primarily intended for CA which are empowered to request all relevant data.

In making the checklist publically available, COEN is pursuing a second objective: to educate the market with a special emphasis on manufacturers of class I products and communicate to stakeholders the criteria adopted by CA for the assessment of validation. Since validation data are usually not made available to end users they can still indirectly benefit from this checklist by challenging the manufactures for instance in their role as a purchaser.

As an added benefit, it is anticipated that the widespread use of the checklist "Assessment of the Validation" will standardise the format of the corresponding part of the technical files thus simplifying considerably the task of CA when assessing validation data.

3.2 Using the Checklist "Assessment of the Validation"

Its use is very similar to the previous checklist so refer first to section 2.2. However there are two prerequisites: first the availability of actual validation data, and second a fairly high level of expertise in the field of the processing of RMD. The checklist "Assessment of Validation" is not primarily intended for end users or procurement personnel. Once again manufactures of class I devices are the main target. In analogy with the recommendation of section 2.2, in order to ascertain complete regulatory compliance they should make parallel use of the full version of EN ISO 14937.

Annex 1

Checklist Instruction for Use (IFU) (based on EN ISO 17664)

		Yes	N.c[i]	No	N.a[ii]
1.0	**General description of the instruction of use.**				
1.1.	Identification of the medical device (MD) (Information on equipment type, identification number, etc.). [iii]				
1.2.	Name and address of the manufacturer (and authorized representative of EU, if applicable).				
1.3.	Equipments or materials necessary in the processes are identified by its generic names or specification instead of trade names, whenever possible.				
1.4.	In terms of risk analysis, the manufacturer took into account the likely training and knowledge of the processor and the equipment likely to be available to the processor.				
2.0	**Information, if the medical device (MD) is affected by cleaning, disinfection and sterilization**				
2.1.	Information for at least one validated method for reprocessing the MD.				
2.2.	Additional information, if processing in accordance with the provided instructions leads to degree of degradation:				
	a. number of reprocessing cycles that can normally be tolerated **or** indication of an end of life criterion				
2.3.	Additional information, if it is critical to the maintenance of the intended function of the medical device and the safety of the user/patient				
	a. details of process steps;				
	b. description of special equipment and/or accessories;				
	c. specification of process parameter and their tolerances.				
2.4.	Additional information, if preparation at the point of use prior to processing is necessary:				
	a. the containers for transportation;				

[i] Not complete (some action to be taken)

[ii] Not applicable

[iii] According 13.3, Annex I MDD, (d) the batch code, preceded by the Word 'LOT' or the serial number and, (e) an indication of the date by which the device should be used and/or year of manufacture should be included in the label.
Under 13.6 of Annex I MDD all details included in section 13.3 should be contained in the IFU with the exception of (d) and (e).

		Yes	N.c[i]	No	N.a[ii]
	b. description of the support systems;				
	c. the maximum period of time that may elapse between use and cleaning;				
	d. description of pre-cleaning-techniques critical to further processing;				
	e. the requirements of the transportation.				
2.5.	Additional information, if preparation before cleaning is necessary				
	a. requirements of capping/opening of ports;				
	b. disassembly of MD;				
	c. leak testing the MD;				
	d. soaking/brushing techniques required;				
	e. ultrasonic treatment of the MD;				
	f. Special tools for disassembly/re-assembly.				
3.0	**Cleaning and disinfection process**				
3.1.	Cleaning process.				
3.1.1.	Information on the validated method for manual cleaning.				
3.1.2.	Information on at least one validated automated method for cleaning.				
	If not, a warning, that an automated method for cleaning is impossible.				
3.2.	Disinfection process.				
3.2.1.	Information on the validated non-automatic method for disinfection.				
3.2.2.	Information on at least one validated automated method for disinfection.				
3.3.	Additional Information, if necessary for the cleaning/disinfection process:				
	a. description of accessories required for cleaning/disinfection;				

		Yes	N.c[i]	No	N.a[ii]
	b. identification and concentration of chemicals/disinfectants required for cleaning/disinfection;				
	c. the contact time of the disinfectant;				
	d. limits and monitoring of chemical residues remaining on the device;				
	e. identification of water quality to be used for the process;				
	f. limits on temperature, concentration of solution(s),exposure time to be used;				
	g. the process temperature(s) to be used;				
	h. the techniques to be used including rinsing.				
4.0	**Drying process**				
4.1.	Additional information, if necessary for the validated drying-process:				
	a. accessories required for the drying process;				
	b. maximum temperature and exposure time for the MD;				
	c. specifications of the drying agent to be used;				
	d. techniques to be used.				
5.0	**Inspection, maintenance, testing and packaging.**				
5.1.	Information on the required methods to confirm the cleanliness and/or performance of MD.				
5.2.	Additional information, if particular maintenance actions for confirmation of proper performance and safety of the MD are needed while any stage of processing:				
	a. method to be used for adjustment/calibration of the MD;				
	b. description of the lubrication to be used;				
	c. performance criteria for the MD to ensure its safe use;				
	d. instructions for re-assembly of the device;				
	e. the method to be used for the replacement of components;				

		Yes	N.c[i]	No	N.a[ii]
	f. description of special tools to be used to maintain the MD;				
	g. the requirements for visual inspection.				
5.3.	Additional information, if a special method packaging or containing during and after sterilization, are necessary.				
6.0	**Sterilization and storage.**				
6.1.	Information on the validated method of sterilization.				
6.2.	Additional information, if necessary:				
	a. the accessories required for sterilization of the MD;				
	b. the identification of maximum values of contaminants in condensate from steam, used in moist heat, EO and/or steam and formaldehyde sterilization;				
	c. the humidity an pressure required for sterilization process;				
	d. a description of post-sterilization techniques/activities;				
	e. a description of the techniques to be used;				
	f. the identification and concentration of the sterilant required for the sterilization process;				
	g. the minimum holding or exposure time of sterilant;				
	h. the required temperature of the sterilant;				
	i. the pressure required for the sterilization process.				
6.3.	Information on the time or condition of storage of the reprocessed MD prior to use.				

Annex 2

Checklist for the ASSESSMENT OF THE VALIDATION of the reprocessing of reusable medical devices based on EN ISO 14937 (1) **(version 1.0.1 18.09.2013)**

		Yes	Nc[iv]	No	N/A[v]
1.0	**General**				
	Description of the device to be **reused**				
2.0	**Validation**				
2.1.	**Validation plan**				
2.1.1.	Description of the objective of the validation considering the use of the device.				
2.1.2.	List of standards used for validation				
2.1.3.	Risk analysis considerations (for instance: nature of the device, intended use, likely training and knowledge of the users, equipment available in the intended environment)				
2.1.4.	Selection of Validation Device or Process Challenge Device (PCD) with sound **rationale** aimed at **reproducing the conditions of a reuse** and not solely first use.				
2.1.5.	Rationale used for the process definition is explained and documented. See EN ISO 14937 (1), annexes A, B, C and D: i. Selection of microorganisms (annex A) ii. Approach: 1. Inactivation of the microbial population in its natural state (**bioburden-based** method, annex B) 2. Inactivation of a reference microorganism and a knowledge of bioburden on product items to be sterilized (**combined bioburden/biological indicator** based method, annex C) 3. Inactivation of reference microorganisms (**overkill** method, annex D)				
2.2.	**Preprocessing**				
2.2.1.	Equipment to be used in the **preprocessing**, including any ancillary items, is specified				

[iv] Not complete (some action to be taken)

[v] Not applicable

		Yes	Nc[iv]	No	N/A[v]
2.2.2.	Instructions for preprocessing are specified or referenced				
2.3.	**Validation of the cleaning/disinfection**				
2.3.1.	**Installation Qualification (IQ)** *(IQ, see EN ISO 14937 section 9.2, is undertaken to demonstrate that the sterilization equipment** and any ancillary items have been supplied and installed in accordance with their specification. (** basically also applicable to cleaning/disinfection process) See also* (2)				
2.3.1.1.	***Equipment*** to be used in the cleaning/disinfection, including any ancillary items, is specified.				
2.3.1.2.	***Equipment*** to be used in the cleaning/disinfection is compliant with ***IEC 61010-2-040*** ("Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials")				
2.3.1.3.	***Equipment*** to be used in the cleaning/disinfection is compliant with ***EN ISO 15883-ff*** (2) (3) (4)				
2.3.1.4.	***Operating procedures*** for the cleaning/disinfection equipment are specified				
2.3.1.5.	***Installation conditions*** for the cleaning/disinfection equipment are specified (location, instructions for installation, calibration status of all instrumentation etc.)				
2.3.1.6.	***Validation status*** of the equipment with reference to records of the quality management system (QMS) for the cleaning/disinfection equipment **or** validation steps and criteria are specified				
2.3.2.	**Operational Qualification (OQ)** *(see EN ISO 14937, section 9.3, OQ is carried out either with unloaded equipment or using appropriate test materials to demonstrate the capability of the equipment to deliver the cleaning/disinfection process that has been defined*				
2.3.2.1.	***Validation status*** of the cleaning/disinfection equipment with reference to records of the quality management system (QMS) for the cleaning/disinfection equipment **or** validation steps and criteria are specified				
2.3.3.	**Performance Qualification (PQ)** *(see EN ISO 14937, section 9.4, PQ is the stage of validation that uses **product** to demonstrate that the equipment consistently operates in accordance with predetermined criteria and the process yields product that is sterile and meets the specified requirements*				
2.3.3.1.	Steps and criteria are specified for the ***effectiveness of cleaning*** of either: a) the Ninhydrin method[vi] b) the modified OPA-method (o-Phtaldialdehyd)[vi]) semi-quantitative methods (sampling: swab method or flushing method) [vi] d) other				

[vi] See EN ISO 15883-1 Appendix C

		Yes	Nc[iv]	No	N/A[v]
2.3.3.2.	For information only (no scoring), please check what approach has been used: ☐a) the Ninhydrin method [vi] [vi] ☐b) the modified OPA-method (o-Phtaldialdehyd) [vi] ☐c) the semi-quantitative methods (sampling: swab method or flushing method) [vi] ☐d) other methods				
2.3.3.3.	Steps and criteria are specified for the ***determination of the log reduction*** of either: a) the bioburden b) the microbial reference organism and the bioburden c) the microbial reference organism				
2.3.3.4.	For information only (no scoring), please check what approach has been used: ☐a) the bioburden ☐b) the microbial reference organism and the bioburden ☐c) the microbial reference organism				
2.4.	**Validation of the sterilization**				
2.4.1.	**IQ**				
2.4.1.1.	***Equipment*** to be used in the sterilization, including any ancillary items, is specified.				
2.4.1.2.	***Equipment*** to be used in the sterilization is compliant with ***IEC 61010-2-040*** ("Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials")				
2.4.1.3.	***Equipment*** to be used in the sterilization is compliant with ***EN 285*** *(Sterilization - Steam sterilizers - Large sterilizers)* ***or EN 13060*** *(Small steam sterilizers)*				
2.4.1.4.	***Operating procedures*** for the sterilization equipment are specified				
2.4.1.5.	***Installation conditions*** for the sterilization equipment are specified (location, instructions for installation, calibration status of all instrumentation etc.)				
2.4.1.6.	***Validation status*** of the sterilization equipment with reference to records of the quality management system (QMS) **or** validation steps and criteria are specified				
2.4.2.	**OQ**				
2.4.2.1.	**Validation status** with reference to records of the quality management system (QMS) for the sterilization equipment				
2.4.3.	**PQ**				
2.4.3.1.	Steps and criteria are specified for the ***determination of the log reduction*** of either: a) the bioburden b) the microbial reference organism and the bioburden				

		Yes	Nc[iv]	No	N/A[v]
	c) the microbial reference organism				
3.0	**Validation data**				
3.1.	**Preprocessing**				
3.2.	**Validation of the cleaning/disinfection**				
3.3.	**IQ/OQ**				
3.3.1.	**IQ/OQ data** are available for cleaning/disinfection and sterilization **or** a **reference to records** showing that the cleaning/disinfection process was currently validated				
3.4.	**PQ**				
3.4.1.	Data on the attainment of the defined ***physical and chemical parameters***, within specified tolerances, throughout the ***cleaning/disinfection*** load. See [vii]				
3.4.2.	Data on the **effectiveness of cleaning** of either: a) the Ninhydrin method [vi] b) the modified OPA-method (o-Phtaldialdehyd) [vi] c) semi-quantitative methods (sampling: swab method or flushing method) [vi] d) other see [vii]				
3.4.3.	Data on the ***determination of the log reduction*** of the ***cleaning/disinfection*** are available and interpretable relative to either: a) the bioburden b) the microbial reference organism and the bioburden c) the microbial reference organism see [vii]				
3.5.	**Validation of the sterilization**				
3.5.1.	**IQ/OQ data** are available for sterilization OR a reference to records showing that the sterilization process was currently validated				
3.5.2.	**Data** on the attainment of the defined ***physical and/or chemical conditions***, within specified tolerances, throughout the sterilization load according to EN ISO 14937 section 9.4.4 are available				
3.5.3.	**Data** on the ***determination of the log reduction*** of the ***sterilisation*** are available and **interpretable** relative to either: a) the bioburden b) the microbial reference organism and the bioburden				

[vii] For this purpose (2), (3) or (4) can be used as a reference for PQ validation depending on the device to be reprocessed

		Yes	Nc[iv]	No	N/A[v]
	c) the microbial reference organism				
3.5.4.	**Data** on the log reduction of the ***sterilization*** bioburden or the microbial reference organism are specified according to EN ISO 14937 section 9.4.5 are available				
3.6.	**Review of validation data**				
3.6.1.	Statistical relevance of data is reviewed				
3.6.2.	The overall process (cleaning/disinfection/sterilisation) guarantees a log reduction greater or equal to 6				
3.6.3.	The reprocessing is declared validated				
3.6.4.	Report summarizing point 3.0				

1. EN ISO 14937 "Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.

2. EN ISO 15883-1 “Washer-disinfectors - Part 1: General requirements, terms and definitions and tests”.

3. EN ISO 15883-2 „Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.”.

4. EN ISO 15883-4 “Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes”.