B.2 Reprocessing instructions (reusable medical devices)

Manufacturer: <Manufacturer name> **Method code:** <ref.> **Symbol:** <sym>

Device(s): <list by catalogue number and device description, or generic type>

WARNINGS:	<warnings re inappropriate chemicals, parameters, points of particular attention
Limitations on reprocessing:	<indication of number of reprocessing cycles permitted, or other indicator of end of life>

INSTRUCTIONS	
Point of use:	<instructions/cautions>
Preparation for decontamination:	<instructions/cautions>
Cleaning: Manual	<instructions/cautions. Include equipment/materials/parameters>
Cleaning: Automatic	<instructions/cautions. Include equipment/materials/parameters>
Disinfection:	<instructions/cautions. Include equipment/materials/parameters>
Maintenance, Inspection and Testing:	<instructions/cautions. Include equipment/materials/parameters>
Packaging:	<instructions/cautions. Include materials/methods>
Sterilization:	<instructions/cautions. Include equipment/materials/parameters>
Storage:	<instructions/cautions>

Additional Information:	<Any other information considered helpful>
Manufacturer contact:	<Contact information for further information>

The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing a device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process. Likewise any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Date issued: <date>

Notes for use:

1) Instructions should be clear and concise.

2) Reference to materials and equipment should be generic where possible.

3) Instructions for disassembly/assembly, maintenance and inspection/test may be documented separately (these instructions are more likely to be specific to a particular device, whereas other instructions are more likely to apply to a group or family of devices)

4) All sections of the table require an entry, "no particular requirements", "not applicable" etc. can be used.

5) The symbol field is optional, it may be used to refer to the instructions from markings on the device or its packaging.

B.3 Example template

Manufacturer: ACME Medical Method code: ACME1 Symbol: 

Device(s): All re-useable surgical instruments supplied by ACME Medical comprising fixed assemblies (no moving parts) and simple hinged assemblies, excluding those containing aluminium alloy.

NOTE Aluminium alloy may be recognised by bright coloured (red, blue, green, yellow) coatings on metallic components.

WARNINGS:	Aluminium based instruments are damaged by alkaline (pH >7) detergents and solutions. Long narrow cannulations and blind holes require particular attention during cleaning. Do not exceed 150 °C
Limitations on reprocessing:	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS	
Point of use:	Remove excess soil with disposable cloth/paper wipe.
Containment and transportation:	No particular requirements. It is recommended that instruments are reprocessed as soon as is reasonably practical following use.
Preparation for cleaning:	No particular requirements. Disassembly not required.
Cleaning: Manual	Equipment: Detergent (example), brush, running water Method: 1 Rinse excess soil from instrument (Temp < 30 °C) 2 Using brush apply detergent solution to all surfaces ensuring that hinged instruments are cleaned in both open and closed positions. NOTE Clean cannulations and holes using an appropriate brush ensuring that full depth of the feature is reached. 3 Rinse under clean running water for 3 minutes. Ensure that running water passes through cannulations, and that blind holes are repeatedly filled and emptied.
Cleaning: Automatic	Equipment: Washer/disinfector, detergent (name) 1 Load instruments such that hinges are open and cannulations and holes can drain. 2 Run standard cycle, minimum 5 minutes wash and 3 minutes rinse. 3 When unloading check cannulations, holes etc for complete removal of visible soil. If necessary repeat cycle or use manual cleaning.
Disinfection:	Disinfectant solution (name) may be used in accordance with label instructions. If automatic cleaning is employed, a final rinse at 80 °C for 10 minutes may be used.
Maintenance:	Apply a small quantity of surgical grade lubrication oil to hinges. Discard blunt or damaged instruments.

Inspection and Function Testing:	Hinged instruments: Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action. All instruments: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check instruments with long slender features (particularly rotating instruments) for distortion. Where instruments form part of a larger assembly, check assembly with mating components.
Packaging:	Singly: A standard polyethylene/Tyvek pouch may be used. Ensure that the pack is large enough to contain the instrument without stressing the seals. In sets: Instruments may be loaded into dedicated instrument trays, or general-purpose sterilisation trays. Ensure that cutting edges are protected, and do not exceed 12 Kg per tray. Wrap the trays using ..... and the AAMI CSR double wrap method.
Sterilization:	Vacuum autoclave, minimum of 3 minutes at 134 °C. Do not exceed 150 °C
Storage:	No particular requirements
Additional Information:	When sterilising multiple instruments in one autoclave cycle ensure that the sterilizer manufacturer's stated maximum load is not exceeded.
Manufacturer contact:	See brochure for telephone and address of local representative or telephone (44) 123 456 789.

The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing a device for re-use. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This normally requires validation and routine monitoring of the process. Likewise any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this European standard and EU Directives

Clauses/sub-clauses of this European Standard	Corresponding annex/paragraph of Directive 93/42/EEC	Remarks
2	/	The definitions provided complement those in Directive 93/42/EEC
3, 4	13.6h	/
Annexes	/	Guidance is given in annexes A and B

Bibliography

[1] ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization.*

[2] EN 285:1996, *Sterilization — Steam sterilizers — Large sterilizers.*