

Guideline No.02

November 2011

Check List for Procurement of Medical Devices pursuant to EN ISO 17664:2004

This checklist has been compiled in order to ensure the possibility of reprocessing with the equipment available in the Reprocessing Unit for Medical Devices prior to purchase.

Department where medical device (MD) is to be used	
Contact person	
Telephone	
Email	
Manufacturer's name	
Contact person	
Telephone	
Email	
Postal address	
Medical device designation	
Article Number	
Serial Number, if applicable	
Intended use	
Invasive	🗌 yes 🗌 no
Risk class as per Robert Koch Institute (RKI)	non-critical Semi-critical A B B
The MD construction has the following special features	 adhesive joinings contact surfaces between different metal alloys anodised surfaces non-ferrous metal light metal carbon fibres heat-sensitive materials
Remarks /other	
Are the following documents available?	
CE mark/conformity declaration /certificate	🗌 yes 🗌 no
Prevalidation or test report	🗌 yes 🗌 no

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Article list for accessories	🗌 yes	no
Training materials (CD-Rom, etc.)	🗌 yes	no
Repairs reference list	🗌 yes	no
Detailed reprocessing instructions as per EN ISO 17664 in national language	🗌 yes	no
Detailed operating instructions (national language)	🗌 yes	no

Must device be dismantled or assembled for reprocessing?	🗌 yes 🗌 no	
If yes, give description		
Precleaning needed?	🗌 yes 🗌 no	
If yes, give description		
Ultrasonic treatment possible?	🗌 yes 🗌 no	
Manual reprocessing needed?	🗌 yes 🗌 no	
If yes, give description		
Automated cleaning possible?	🗌 yes 🗌 no	
Permitted pH range:	pH to	
Permitted temperature range:	to °C	
Permitted number of reprocessing cycles:	X	
The following detergents are being currently used in the establishment	suitable	not suitable
List of other recommended/device-compatible detergents		
Certain constituents (e.g. softeners) excluded, if yes, which?	🗌 yes 🗌 no	
Accessories needed for reprocessing or transport, if yes, which?	🗌 yes 🗌 no	
Automated disinfection possible	thermal chemoth	ermal 🗌 chemical
Permitted temperature range	to °C	

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The following disinfectants are being currently used in the establishment	suitable	not suitable

List of other recommended/device-compatible disinfectants	Expert proved effectiveness
	🗌 yes 🔲 no
	🗌 yes 🗌 no
	🗌 yes 🔲 no
Care products needed?	🗌 yes 🗌 no
If yes, give description	
Special requirements for MD packaging.	🗌 yes 🔲 no
If yes, give description	
Steam sterilization (pulsed vacuum method) possible?	yes no
Permitted sterilization temperature(s)	□ 121 ℃ □ 134 ℃
Low-temperature processes possible?	🗌 yes 🔲 no
If yes, give description	
Spare parts supply possible?	🗌 yes 🔲 no
Supply of samples possible?	🗌 yes 🔲 no
Date, manufacturer's signature	
Date, user's signature	
Date, infection control officer's signature	
Date, CSSD manager's signature	
Devices accepted for reprocessing	🗌 yes 🗌 no