

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	<input type="checkbox"/> yes <input type="checkbox"/> no
Risk class as per Robert Koch Institute (RKI)	non-critical <input type="checkbox"/> semi-critical A <input type="checkbox"/> B <input type="checkbox"/> critical A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/>
The MD construction has the following special features	<input type="checkbox"/> adhesive joinings <input type="checkbox"/> contact surfaces between different metal alloys <input type="checkbox"/> anodised surfaces <input type="checkbox"/> non-ferrous metal <input type="checkbox"/> light metal <input type="checkbox"/> carbon fibres <input type="checkbox"/> heat-sensitive materials
Remarks /other	
Are the following documents available?	
CE mark/conformity declaration /certificate	<input type="checkbox"/> yes <input type="checkbox"/> no
Prevalidation or test report	<input type="checkbox"/> yes <input type="checkbox"/> no

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Article list for accessories	<input type="checkbox"/> yes <input type="checkbox"/> no
Training materials (CD-Rom, etc.)	<input type="checkbox"/> yes <input type="checkbox"/> no
Repairs reference list	<input type="checkbox"/> yes <input type="checkbox"/> no
Detailed reprocessing instructions as per EN ISO 17664 in national language	<input type="checkbox"/> yes <input type="checkbox"/> no
Detailed operating instructions (national language)	<input type="checkbox"/> yes <input type="checkbox"/> no

Must device be dismantled or assembled for reprocessing? If yes, give description	<input type="checkbox"/> yes <input type="checkbox"/> no _____	
Precleaning needed? If yes, give description	<input type="checkbox"/> yes <input type="checkbox"/> no _____	
Ultrasonic treatment possible?	<input type="checkbox"/> yes <input type="checkbox"/> no	
Manual reprocessing needed? If yes, give description	<input type="checkbox"/> yes <input type="checkbox"/> no _____	
Automated cleaning possible?	<input type="checkbox"/> yes <input type="checkbox"/> 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
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
List of other recommended/device-compatible detergents		
Certain constituents (e.g. softeners) excluded, if yes, which?	<input type="checkbox"/> yes <input type="checkbox"/> no	
Accessories needed for reprocessing or transport, if yes, which?	<input type="checkbox"/> yes <input type="checkbox"/> no	
Automated disinfection possible	<input type="checkbox"/> thermal <input type="checkbox"/> chemothermal <input type="checkbox"/> chemical	
Permitted temperature range	_____ to _____ °C	

