

## Requirements for Reprocessing Units for Medical Devices (RUMEDs) in healthcare establishments

Reprocessing unit category	I	II	III
<b>Risk group of medical device (MD) to be reprocessed</b>	Non-critical, semi-critical A, critical A <sup>(1)</sup>	Non-critical, semi-critical A, B, critical A	All groups
<b>Healthcare establishments</b>	e.g. (homes for the elderly / nursing homes, outpatient departments, medical practices <sup>(2)</sup> )	e.g. healthcare establishments without surgical units	e.g. healthcare establishments with surgical units
<b>Quality assurance</b>	Appropriate quality assurance measures	Appropriate quality assurance measures (minimum requirements as per Robert Koch Institute - RKI)	QM system <i>preferably</i> based on, for critical C devices based on EN ISO 13485:2003
<b>Structural requirements</b>	<ul style="list-style-type: none"> <li>- Dedicated area</li> <li>- Preferably with separate unclean / clean/ sterile zones (temporal separation possible)</li> </ul>	<ul style="list-style-type: none"> <li>- Dedicated reprocessing room</li> <li>- Separate unclean/clean/sterile zones <sup>(3)</sup></li> </ul>	<ul style="list-style-type: none"> <li>- Dedicated premises</li> <li>- Separate unclean/clean/ sterile premises <sup>(4)</sup></li> </ul>
<b>Staff qualifications</b>	Management and staff at least Specialist Course I <sup>(5)</sup>	Management: at least Specialist Course II Staff: at least Specialist Course I	Management and deputies: Specialist Course III Staff: at least Specialist Course I
<b>Technical equipment</b>	<ul style="list-style-type: none"> <li>- If necessary small steam sterilizer (Class B recommended) as per EN 13060</li> <li>- If, necessary ultrasonic cleaning equipment</li> <li>- If necessary, washer-disinfector (WD) as per EN ISO 15883</li> <li>- If necessary, heat sealing machine</li> </ul>	<ul style="list-style-type: none"> <li>- Steam sterilizers (big or small) as per EN 285 or EN 13060</li> <li>- Endoscope WD as per EN ISO 15883</li> <li>- If necessary, rotary sealing machine</li> <li>- If necessary, ultrasonic cleaning equipment</li> </ul>	<ul style="list-style-type: none"> <li>- Steam sterilizers (big) as per EN 285</li> <li>- If necessary, equipment for special sterilization processes (e.g. low-temperature sterilizers)</li> <li>- Endoscope WD as per EN ISO 15883</li> <li>- Rotary sealing machine</li> <li>- Ultrasonic cleaning equipment</li> </ul>

(1) Call for special consideration; (2) with the exception of lumened endoscopes (Cat. II) and surgical procedures (Cat. III), except for management of small wounds; (3) For new endoscopy units – centralisation and separate unclean/clean premises are recommended; (4) For new, extended or converted premises, clean area should meet requirements of ISO class 8 as per ISO 14644-1, as far as possible also for existing establishments; (5) deemed to have been met for degree-level nursing staff or for medical personnel

## Concept for continuing professional development courses for "Reprocessing medical devices in/for healthcare establishments"

COURSE	SPECIALIST COURSE I	SPECIALIST COURSE II	SPECIALIST COURSE III
TARGET GROUP	Semi-skilled staff and assistants; Dental staff ** or dental assistants	Semi-skilled staff with special duties (e.g. able to release MDs) and graduates with responsibility for a section	Managers and deputy managers
EXTENT	80 hours: theory and practical exercises	80 hours: 40 hours theory 16 hours practical exercises 24 hours practical work	80 hours: 40 hours theory 40 hours concluding assignment
ADMISSION REQUIREMENTS	None	Successful completion of Specialist Course I. and at least 1 year's experience in a MD reprocessing unit <b>or</b> Suitably recognised Qualification (in accordance with national requirements) <b>and</b> with successful examination on content of Specialist Course I (without attending course)	Suitably recognised Qualification (in accordance with national requirements) and successful completion of Specialist Course II
REQUIREMENT FOR	Management of RUMED Cat. I **, Staff of RUMD Cat. I **, II, III	Managers and deputy managers of RUMED Cat. II Responsibility for section of RUMED Cat. III.	Managers and deputy managers of RUMED Cat. III
DEADLINE FOR COMPLETION	Within 2 years of taking up position	Within 2 years of taking up position	Within 2 years of taking up position
EXAMINATION	Examination of knowledge	Examination and assignment	Examination and final assignment

\* if not covered in specialist OR course, \*\* except for degree-level nursing staff or for medical personnel

Source: Austrian Society for Sterile Supply (ÖGSV), [www.oegsv.com](http://www.oegsv.com)