



## Chemicals for reprocessing Richard Wolf products

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**Manufacturer**



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# 1 Validation chemicals

## NOTE

### Product-specific information

Please follow the information provided in the product-specific instructions for use.

## NOTE

### Regulatory requirements

Reprocess the products taking into account the applicable national requirements.

### General information

Due to the ever increasing and changing regulatory requirements, in particular within the scope of the Medical Device Regulation (MDR EU2017/164), RICHARD WOLF GmbH has carried out an extensive review and assessment of all chemicals approved to date for the reprocessing of its medical products.

In particular, the requirement of testing the efficacy and the interaction of different products cannot be guaranteed given the large variety of the process chemicals used for cleaning, disinfection and additional sterilization, if applicable. For this reason, the previous list (GA-J055 / 2016-12 V1.0) of chemicals approved for the reprocessing of Richard Wolf GmbH is no longer valid with immediate effect.

The manufacturer of the process chemicals undertakes to validate the required evidence with regard to material compatibility and efficacy. To meet the requirements of the instrument manufacturer in accordance with ISO 17664, please refer to section 2 for the chemicals we used for the validated reprocessing steps.

The manufacturer's instructions on exposure time, concentration, and use must be strictly followed. By no means should any residues remain on the instruments. Possible interactions with **other products** cannot be taken into account.

The respective manufacturer remains responsible for supplying all documents on the chemicals, such as instructions for use and safety data sheets.

**Chemicals used by Richard Wolf for validation**

Manufacturer	Trade name	Thermolabile products	Heat-stable products
<i>Manual cleaning</i>			
Chemische Fabrik Dr. Weigert GmbH & Co. KG	Neodisher Medi-Clean		X
ASP	Cidezyme	X	X
<i>Manual disinfection</i>			
STERIS	Revital-Ox® RE-SERT® High Level Disinfectant	X	X
ASP	Cidex OPA	X	X
<i>Machine cleaning</i>			
Chemische Fabrik Dr. Weigert GmbH & Co. KG	Neodisher Medi-Clean		X
Olympus	EndoDET	X	
<i>Machine disinfection</i>			
Olympus	EndoACT	X	
Olympus	EndoDIS	X	
<i>Wipe disinfection for the surfaces of electrical devices</i>			
Metrex™	CaviWipes™		

**Active agents****NOTE****Approval of chemicals not listed**

Reprocessing chemicals consist of a multitude of ingredients designed for optimum compatibility and interaction. Therefore, we cannot provide a general approval of chemicals with material-compliant main active substances. This is the obligation of the manufacturer of the process chemicals.

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Richard Wolf GmbH can confirm the material compatibility of the following main active substances (A-Z):

- Quaternary ammonium compounds (QACs)
- Enzymes
- Acetic acid
- Formaldehyde
- Glutaraldehyde
- Isopropanol
- Peracetic acid
- Phosphates
- Phosphoric acid
- Tensides
- Hydrogen peroxide
- Citric acid