

SURFACE / READY TO USE DISINFECTANTS

CLEANISEPT® WIPES FORTE / MAXI



PROTECT

ALCOHOL-FREE WIPES FOR RAPID DISINFECTION

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Universal, comfortable and time-saving application

Broad, rapid effectiveness and a wide range of applications **in areas with increased effectiveness requirements**

For virucidal disinfection of ultrasound probes for **transvaginal and abdominal examinations**



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PRODUCT DESCRIPTION

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Infection prevention at the highest level



CLEANISEPT WIPES FORTE MAXI

CLEANISEPT WIPES FORTE are alcohol-free, ready to use wipes for virucidal rapid disinfection and cleaning of medical devices.

CLEANISEPT WIPES FORTE enables a practical and time-saving application, especially for the virucidal disinfection and cleaning of ultrasound probes. The wipes are free of alcohol, aldehydes and phenols.



CLEANISEPT WIPES FORTE

CLEANISEPT WIPES FORTE MAXI are particularly suitable for disinfecting and cleaning medium-sized surfaces in areas with increased efficacy requirements due to their large wipes and extensive spectrum of activity. The wipes can be removed individually from the practical packaging with its resealable cover.

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APPLICATIONS AND NOTES

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Acc. to EU Medical Devices Regulation

For rapid disinfection and cleaning of alcohol sensitive medical devices.

CLEANISEPT WIPES FORTE MAXI:

Acc. to Biocidal Products Regulation (BPR)

For rapid disinfection and cleaning of alcohol sensitive medical equipment and surfaces of every type especially in areas with increased efficacy requirements.

Application

Wipe surfaces with CLEANISEPT WIPES FORTE/MAXI until completely wet and allow to dry for the entire contact time.

According to the EU Medical Device Regulation, users/patients are obligated to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the EU Member State in which the user/patient is established.

Application discription

For the preparation of ultrasound probes, the basic hygiene standards (especially regarding personal protective equipment, appropriate hygienic work environment, and hygienic hand disinfection) must be considered.

Pre-cleaning: After removing the protective cover, wipe the probe with a commercially available, germ-free, and lint-free disposable towel previously moistened with water. Enclose the towel in the palm of your hand and rub it evenly over the surface of the probe five times with a little pressure. Ensure complete wetting of the surface. Then, dry the probe with another disposable towel. Dispose of the towel.

Cleaning: Take a CLEANISEPT WIPES FORTE/MAXI towel from the packaging and unfold it in an open palm. Clean the surface, including the handle, with the towel by enclosing it in the palm of your hand and rubbing it evenly over the surface five times with a little pressure. Then, dry the probe with another disposable towel. Dispose of the towel.

Disinfection: Take a second CLEANISEPT WIPES FORTE/MAXI towel from the packaging and unfold it in an open palm. Disinfect the surface, including the handle, with the towel by enclosing it in the palm of your hand and rubbing it evenly over the surface five times with a little pressure. Ensure complete wetting of the surface and let the disinfectant dry over the entire exposure time of 2 minutes. Dispose of the towel.

Drying: After the CLEANISEPT WIPES FORTE/MAXI exposure time has expired, dry the surface of the probe with a disposable towel. Rinsing at the end of the reprocessing process is not necessary; dry wiping has proven to be sufficient. The condition for this is that the reprocessing recommendation is consistently followed.

Application notes

Shelf life after opening: 28 days

Composition

100 g solution contain:

0.4 g alkyl(C₁₂₋₁₆)dimethylammonium chloride,
0.2 g didecyldimethylammonium chloride.

Material compatibility

Wide range of applications on surfaces and medical devices. (see page 6 – 8)
CLEANISEPT WIPES FORTE/MAXI are recommended for the disinfection of ultrasound probes for abdominal and transvaginal examinations from the following manufacturers:

Esaote GmbH
Siemens Medical Solutions
Samsung
Olympus
GE Healthcare
Fujifilm/SonoSite/Aloka/Hitachi

Product status

CLEANISEPT WIPES FORTE: Medical Device

CLEANISEPT WIPES FORTE MAXI: Dual Registration (medical device/biocide)

Precautionary and hazard statements

Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container to approved disposal company or local collection. For professional use only by personnel with corresponding specialist knowledge according to national directives.

Use disinfectants safely.

Always read label and product information before use.

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SPECTRUM OF EFFICACY AND CONTACT TIMES

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SPECTRUM OF EFFICACY AND CONTACT TIMES			1 min	2 min	15 min
Application recommendations for surface disinfection					
bactericidal ¹ , yeasticidal ¹	VAH/EN ²	with mechanical action, dirty conditions	•		
virucidal	EN 14476	dirty conditions	•		
active against polyomaviruses /SV40	EN 16615	clean conditions		•	
Additional test results					
bactericidal	EN 16615	dirty conditions		•	
	EN 13727	dirty conditions	•		
yeasticidal	EN 16615	dirty conditions		•	
	EN 13624	dirty conditions	•		
fungicidal (A. brasiliensis)	EN 13624	clean conditions			•
	EN 16615	clean conditions	•		
active against noroviruses (MNV)	EN 14476	dirty conditions	•		
active against adenoviruses	EN 14476	dirty conditions	•		
active against polioviruses	EN 14476	dirty conditions	•		

1 – including phase 2 stage 1 - and phase 2 stage 2 tests (quantitative suspension tests and practical germ carrier tests)

2 – EN 16615, EN 13624, EN 13727

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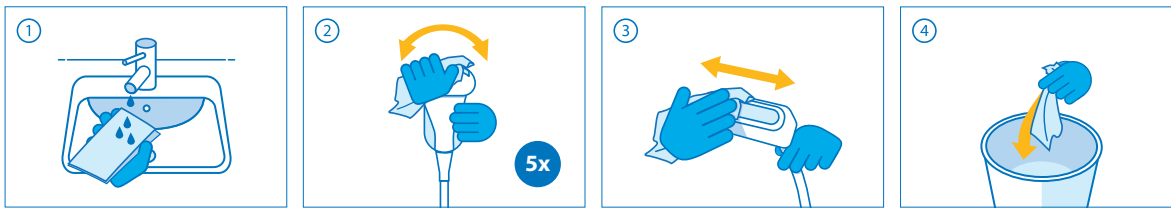
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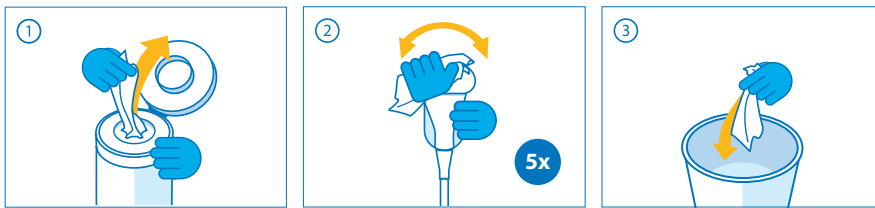
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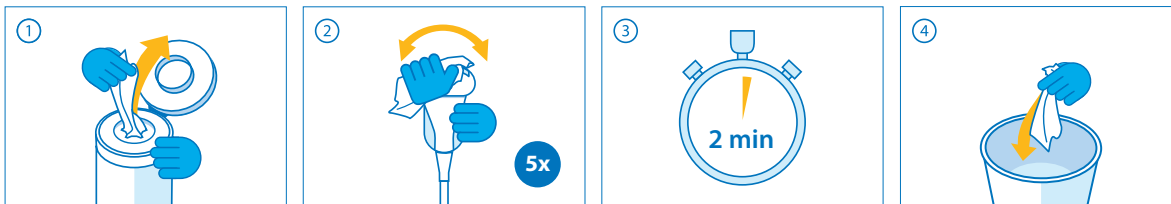
PRE-CLEANING



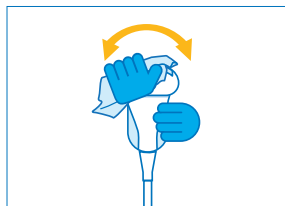
CLEANING



DISINFECTION



DRYING



STORAGE



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MATERIAL COMPATIBILITY

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MATERIAL METALS	not recommended	limited recommended	recommended	APPLICATION PRODUCT EXAMPLE
Stainless steel V2A			<ul style="list-style-type: none"> Medical transport chairs Rollators Toilet chairs 	
Stainless steel V4A			<ul style="list-style-type: none"> 	
Copper	<ul style="list-style-type: none"> 			
Brass	<ul style="list-style-type: none"> 		<ul style="list-style-type: none"> Luer lock adapter Stethoscope (chrome-plated brass) 	
Aluminum	<ul style="list-style-type: none"> 			

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MATERIAL COMPATIBILITY

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MATERIAL PLASTICS: ELASTOMERS	not recommended	limited recommended	recommended	APPLICATION PRODUCT EXAMPLE
PUR (polyurethane)			•	

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MATERIAL COMPATIBILITY

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MATERIAL PLASTICS: THERMOPLASTICS	not recommended	limited recommended	recommended	APPLICATION PRODUCT EXAMPLE
PE-HD (polyethylene-High Density)			●	Storage and transport containers
PE-LD (polyethylene-Low Density)			●	
POM (polyoxymethylene)			●	Seat shells
PA (polyamide)			●	X-ray chutes
PP (polypropylene)			●	Hose lines
PVC (polyvinyl chloride)			●	Hose lines
PMMA (polymethyl methacrylate)			●	Acrylic and plexiglass
PEI (Polyetherimide)			●	Sterilization and transport containers
PSU (polysulfone)		●		
PC (Polycarbonate e.g. Makrolon)	●			Ultrasound devices
	●			ECG devices, EEG devices
	●			EEG devices
	●			CT devices
ABS (acrylonitril-butadiene-styrene)	●			Patient monitoring monitors
	●			Medical keyboards and mice

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PURCHASING INFORMATION

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Product	Single unit	Delivery unit	Content	Wipe size	REF
CLEANISEPT WIPES FORTE	Dispenser	12	100 wipes	14 x 20 cm	00-235-D100
CLEANISEPT WIPES FORTE MAXI	Package	6	100 wipes	20 x 22 cm	00-235-T100

The availability of the products and container sizes depend on a successful national registration.



CE 0482

CERTIFICATIONS



Dr. Schumacher is certified according to DIN EN 13485, DIN EN ISO 9001, DIN EN ISO 14001, BS OHSAS 18001, has a validated environment management system according to EMAS and is a member of IHO, VCI, BAH, DGSV and of the DGKH.