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04.05.2026

Urgent Safety Information

Recall due to microbial contamination of MANUSHIELD CLEANER

Dear Customers, Dear Users,

Dr. Schumacher GmbH is issuing this customer communication to inform you about microbial contamination identified in batches (see appendix) of MANUSHIELD CLEANER. The microbial contamination is limited to this product; no other products are affected.

This notice will be reported to the competent authorities as a Field Safety Corrective Action (FSCA). Due to the nonconformity, however, it is important to emphasize that there was no risk to patient safety at any time. The reason is that the product is used solely as a cleaner in the initial steps of reprocessing and is subsequently followed by disinfection and sterilization processes.

Item	Details
Type of action	Recall of batches of the product MANUSHIELD CLEANER (see appendix)
Concerning	MANUSHIELD CLEANER
Date of this letter	14 April 2026
Sender	Dr. Schumacher GmbH Am Roggenfeld 3 34323 Malsfeld Germany
Addressee	Users, operators, purchasing departments, reprocessing units for medical devices (AEMP), hygiene officers, distributors, and other recipients of affected stock of the product MANUSHIELD CLEANER
Identification of the affected medical devices	Product: MANUSHIELD CLEANER REF: 00-104-020-* and REF: 00-104-050-* Product type: Cleaner for manual cleaning of surgical instruments, flexible endoscopes, and rigid endoscopes Affected batch: Batches (see Appendix 1)

Description of the problem, including the identified cause

The batches (see appendix) of the product MANUSHIELD CLEANER contain microbial contamination that may lead to contamination of medical devices cleaned with these batches. As the reprocessing of medical devices always includes at least one disinfection and/or sterilization step after cleaning, and this step has been demonstrated to ensure a standards-compliant microbial reduction on medical devices cleaned with the affected batches of MANUSHIELD CLEANER, there is no increased risk to patient safety when the product is used as intended. Nevertheless, due to the microbial contamination, the affected batches do not comply with specifications.

The root cause analysis has not yet been completed at this time.

Risk to patients, users, or third parties

MANUSHIELD CLEANER is a cleaner without disinfecting effect and is used as part of a multi-step reprocessing procedure in which at least one disinfection and/or sterilization step follows the cleaning step with the affected product, as intended.

The disinfection and/or sterilization step ensures a standards-compliant microbial reduction on the medical devices cleaned with the affected batches of MANUSHIELD CLEANER. Therefore, when the product is used as intended, there is no increased risk to patient safety.

The reporting user confirmed to the manufacturer that the flexible endoscopes reprocessed with the microbially contaminated product showed no microbial contamination after completion of reprocessing and were free of objection.

In addition, during the cleaning process the user is equipped with appropriate personal protective equipment due to the microbial contamination of the unclean medical devices, so the risk posed by the product to the user or third parties is also considered low. Nevertheless, due to the microbial contamination, the affected batches do not comply with specifications.

What actions must be taken by the addressee?

Do not continue using affected stock with immediate effect.

Immediately identify all inventory of MANUSHIELD CLEANER bearing the batches listed in Appendix 1 and clearly quarantine it from further use.

Ensure that affected stock is neither distributed internally nor supplied to third parties nor used further.

Immediately inform all relevant internal areas (in particular AEMP, endoscopy, hygiene, purchasing, and warehouse) as well as any third parties you may have supplied about this Urgent Safety Information.

Check whether the product has already been used.

Dr. Schumacher GmbH

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Executive Board

Dierk Schumacher
Dirk Hamenstädt
Tim Steffens

Bank Details

Commerzbank Kassel · DE56 5204 0021 0260 3165 00 · COBADEFFXXX
Volksbank Kassel-Göttingen · DE24 5209 0000 0000 0681 01 · GENODE51K51
DZ Bank AG · DE28 3006 0010 0000 2291 12 · GENODEDDXXX

Registration

Amtsgericht Fritzlar HRB 11035
USt-IdNr. DE 113 367 704

If yes: Carry out a risk-based assessment involving your hygiene / medical device responsible persons. (If the subsequent disinfection / sterilization has been properly performed, the risk is considered low.)

Handling of affected stock:

Outside the EU: Destroy the goods after consultation with us and document the destruction.

Within the EU: Please return the goods to us. Destruction on site may also be possible after consultation with the manufacturer and with appropriate confirmation.

Replacement or credit note will be provided by Dr. Schumacher GmbH.

Please return the attached acknowledgement of receipt no later than 19th of May 2026 to mp-vigilanz@schumacher-online.com.

Timeline for implementation of the action

Milestone	Date / description
Immediate	Immediate stop of use and quarantine of the affected batches of the product upon receipt of this information
Feedback to manufacturer by	19 th May 2026
Collection / return / replacement by	12 th June 2026
Expected completion of the action by	19 th June 2026

Forwarding of the information described here

Please ensure within your organization that all users of the above-mentioned products and any other persons who need to be informed become aware of this Urgent Safety Information.

If you have supplied the products to third parties, please forward a copy of this information or inform the contact person named below.

Please retain this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this Urgent Safety Information.

Contact person

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Director Science & Innovation, PRRC
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We thank you for your support and apologize for the inconvenience caused.

Yours sincerely,

Dr. Harald Büttner
Director Science & Innovation, PRRC
04 05 20 26 16 48 28

Dr. Schumacher GmbH
Dr. Harald Büttner
Director Science & Innovation, PRRC

MANUSHIELD CLEANER

Product list: Articels and Lots from MANUSHIELD CLEANER

Product-REF	LOT	Product-REF	LOT	Product-REF	LOT
00-104-020-02	502760	00-104-050-01	503046	00-104-050AR-01	508143
	503524		503047		509636
	503681		503049		
	504156		503446		
	504333		503835		
	504506		503836		
	504970		504101		
	505254		504701		
	505650		504898		
	506082		505168		
	506484		505169		
	506911		505404		
	507340		505651		
	507802		506134		
	508640		506135		
			506390		
			506485		
			506912		
			507339		
			507803		
			507804		
			508144		
			508641		
			509412		
			509637		
			511246		

Desinfektionsmittel vorsichtig verwenden. Vor Gebrauch stets Etikett und Produktinformationen lesen.