Summary of the disinfecting performance

neodisher Septo DN

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1. Introduction

neodisher Septo DN is a product designed and recommended for high level - disinfection of flexible endoscopes and thermolabile instruments in washer disinfectors.

neodisher Septo DN is bactericidal, fungicidal, mycobactericidal and virucidal.
The automated reprocessing process with neodisher MediClean forte and **neodisher Septo DN** fulfils the requirements of DIN EN ISO 15883-4 with regard to a germ reduction of > 9 log 10 in the total process.
The disinfecting activity has been tested and confirmed according to DIN EN 14885.
neodisher Septo DN conforms to the requirements on disinfectants for the disinfection of flexible endoscopes in washer disinfectors according to DIN EN ISO 15883-4.

2. Methods

In order to proof the disinfectant efficacy, the European standards of CEN/TC 216 "Chemical disinfectants and antiseptics" for verifying the disinfecting performance of chemical disinfectants are appropriate and are uniform throughout Europe.
The application of the respective standards is described in EN 14885.

Table 1: Application of standards for instrument disinfection according to EN 14885

Type of activity	Phase, Step	Standards for Instrument disinfection
bactericidal	2,1	EN 13727
	2,2	EN 14561
fungicidal	2,1	EN 13624
	2,2	EN 14562
mycobactericidal	2,1	EN 14348
	2,2	EN 14563
virucidal	2,1	EN 14476
	2,2	EN 17111

All tests are performed under so-called "clean conditions," as the product is used for disinfection after cleaning.
For the German market, the virucidal tests are also performed according to the methods of **RKI/ DVV**.
The total germ reduction of the automated reprocessing process with neodisher MediClean forte and **neodisher Septo DN** is tested according ISO/TS 15883-5:2005 to prove the confirmation of DIN EN 15883-4.

All standards are performed in the currently published version (see also points 5 and 6).

3. Results

3.1 Bactericidal, fungicidal, mycobactericidal and virucidal activity

As a result of the tests the following minimum effective concentrations have been investigated:

The test conditions:

temperature: **55°C**
soiling: **clean conditions**
contact time: **5 minutes**

Table 2: Summary oft the minimum effective concentrations

Efficacy	Method	Effective concentration	Expertise no	date of issue
bactericidal	EN 13727	0.50%	GD 4010/05-16	09.08.2016
	EN 14561	0.1%	GD 4010/01-16	17.09.2014
fungicidal	EN 13624	0.1%	GD 4010/02-16	17.09.2014
	EN 14562	1.0%	GD 4010/02-16	17.09.2014
myco-bactericidal	EN 14348	0.1%	GD 4010/03-16	17.09.2014
	EN 14563	0.8%	GD 4010/03-16	17.09.2014
virucidal	EN 14476	1.0%	GD 4010/07-16	23.09.2014
	EN 17111	0.75%	GD 4089-03-20a	24.01.2020
	DVV/ RKI (clean and dirty conditions)	1.0%	GD 4010/06-16	01.06.2016

3.2 Total germ reduction of the process

The total germ reduction of the automated reprocessing process with neodisher MediClean forte and **neodisher Septo DN** is tested according ISO/TS 15883-5:2005 to prove the confirmation of DIN EN 15883-4.

According to Test Report GD 4010/08-16 dated 2014-12-19 (HygCen), the process achieves a **>9 log reduction.**

4. Summary and evaluation

According to the above test results, **neodisher Septo DN** can be recommended using the following conditions:

bactericidal, fungicidal, mycobactericidal and virucidal activity	10 ml/l (1.0 %), 55 °C, 5 min

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5. Literature

1. EN 14885:2018, Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics
2. EN 13727: 2015, Chemical disinfectants and antiseptics– Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area– Test method and requirements (phase2, step1)
3. EN 14561:2006, Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)
4. EN 13624:2013 Chemical disinfectants and antiseptics– Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area– Test method and requirements (phase2, step1)
5. EN 14562:2006, Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)
6. EN 14348:2005, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1)
7. EN 14563:2008, Chemical disinfectants - Quantitative carrier test for evaluation of mycobactericidal activity of chemical disinfectants for instruments used in medical area (phase 2, step 2)
8. EN 14476:2018, Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2/step 1)

9. EN 17111:2018, Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
10. Guideline of "Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V" (DVV) and the Robert Koch Institute (RKI) (dated 01.12.2014)
11. DIN EN 15883-4: 2009 Washer disinfectors - Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
12. ISO/TS 15883-5:2005 Washer disinfectors - Test soils and methods for demonstrating cleaning efficacy

6. Microbiological expert reports

- **GD 4010/01-16:** bactericidal activity according to EN 14561:2006, 17.09.2014
- **GD 4010/05-16:** bactericidal activity according to EN 13727:2012+A1:2015, 09.08.2016
- **GD 4010/02-16:** fungicidal activity according to EN 13624:2013, 17.09.2014
- **GD 4010/02-16:** fungicidal activity according to EN 14562:2006, 17.09.2014
- **GD 4010/03-16:** mycobactericidal according to EN 14348:2005, 17.09.2014
- **GD 4010/03-16:** mycobactericidal according to EN 14563:2008, 17.09.2014
- **GD 4010/07-16:** virucidal activity according to EN 14476:2013, 23.09.2014
- **GD 4089/03-20a:** virucidal activity according to EN 17111:2018, 24.01.2020
- **GD 4010/06-16:** virucidal activity according to DVV/RKI:2014, 24.01.2020