

# TEST REPORT

## NOPA INSTRUMENTS

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The preparation test of nopa instruments and sterile containers at Sermax AG in Steffisburg from 8th to 12th August 2016:

### **Table of Contents**

1. Description
2. Test of Medical Devices
3. Assessment
4. Deviations / Recommendations
5. Process parameters RDG
6. Process parameter steam sterilization
7. Datasheets process chemistry
8. Certificate ISO 13485

This test determines whether the instruments and containers are compatible with the processes of sermaX AG.

## 1. Description

This test determines whether the instruments and containers are compatible with the processes of sermaX AG.

The instruments were identified as follows:

### 1.1 Ultrasonic bath:

- Detergent neodisher IR of the company Dr. Weigert
- Concentration: 4 %

The concentration was 0.5% which was higher than the usual 3.5%.

Grounds: Maximum load of the instruments

- Temperature: 50 °C
- Exposure time: 12 min.

The exposure time was increased from the recommended 5 minutes to 12 minutes. Grounds: Maximum load of the instruments

### 1.2 RDG process

- The instruments were washed with the Standard Program 1
- Detergent used: neodisher MediClean forte
- Rinse used: neodisher MediKlar special

The exact process parameters and data sheets of the process chemistry can be seen in the appendix Process Flow RDG.

### 1.3 Inspection, maintenance and packaging of the instruments

- Inspection of surfaces for integrity
- Checking the function
- Care of the joints using Pflegeöl Sterilit of Aesculap
- Packing in foil sachet of the Company Stericlin and subsequent welding with a sealer

### 1.4 Steam sterilization process

- Steam sterilization at 134 °C and 18 minutes

The exact process parameters are shown in the appendix Process Flow Steam Sterilization.

The sterile containers were treated as follows:

### 1.5 RDG process

- The containers were washed with the Container Program. 3

The exact process parameters are shown in the appendix Process Flow RDG

### 1.6 Inspections

- Inspection of the surface for integrity
- Checking the function

### 1.7 Steam sterilization process

- Steam sterilization at 134 °C and 18 minutes

The exact process parameters are shown in the appendix Process Flow Steam Sterilization.

## 2. Test

### 2.1 Instruments

The following instruments were used in this test:

Designation	Article No.	Amount
Anatomic tweezers, standard, straight, 14.5 cm	AB 050/14	2 units
Surgical tweezers 1 x 2 teeth, standard, straight, 14.5 cm	AB 060/14	2 units
Scissors st/sp, standard, straight, 14.5 cm	AC 020/14	2 units
Scissors st/st, standard, straight, 14.5 cm	AC 010/14	2 units
Bandage scissors Lister, angled, 14 cm	AC 567/14	2 units
Haemostat Rochester-Pean, straight, 14 cm	AA 200/14	2 units
Needle Holder Mayo Hegar, 16 cm	AE 400/16	2 units
Kidney dish, 170 mm	KU 302/17	2 units
Round bowl, 80x40 mm	KU 300/08	2 units



Upon delivery of the instruments a visual and functional test was performed. The instruments are in a qualitatively very good condition. No defects have been detected on the instruments.

The instruments were first treated using an ultrasonic bath. After 12 minutes in the solution, the instruments were rinsed with deionized water. In the visual inspection no qualitative changes and/or discolouration were observed.

Divided into sieves, the instruments were added to the RDG process. After the RDG process our employees examined the instruments under a magnifying glass: No defects could be found.

During the subsequent function test no abnormalities were noted either.

Packed and heat-sealed in foil flat bags the instruments were added to the steam sterilization process. After the process the packaging was inspected for spots and stains: Again, nothing was found.

The instruments were unpacked and transported back to the cleaning and disinfection area. Repetition of a visual and functional test. Finally, the instruments were put through the entire preparation process 10x. At each partial step, the instruments were tested again.

## 2.2 Sterile container

The following two containers were available for this test:

Designation	Article No.	Amou
Non-perforated pan, 285 x 280 x 135 mm	KYE 286/13	1
Perforated lid, 285 x 280 mm	KYE 280/02	1
Non-perforated pan, 580 x 280 x 260 mm	KYE 287/26	1
Perforated lid, 580 x 280 mm	KYE 280/52	1



Upon delivery of the sterile container, a visual and functional test was conducted. The sterile containers are in a qualitatively very good condition.

*It has been found, however, that the article number is not shown on the lids or on the trays (more in Chapter 3). Regarding material and processing no defects have been detected.*

Correctly positioned on the cleaning trolley for container, these were added to the RDG process. After the RDG process our employees examined the sterile container under a magnifying glass: No defects could be found.

During the subsequent function test no abnormalities were noted.

The lids were equipped with disposable paper filter and added to the steam sterilization process. After the process the sterile containers were inspected for spots and stains: Again, nothing was found.

The sterile containers were unpacked and transported back to the cleaning and disinfection area. Repetition of a visual and functional test. These were subsequently put through the entire treatment process 10x. At each sub-step, the sterile containers were examined again.

No changes were observed in the material of the sterile containers. After repeated processing they are still unchanged and are in a qualitatively very good condition.

These products passed the tests and are considered very good.

### 3. Assessment

#### 3.1 Instruments

No changes were observed in the material of the instruments after 10 process runs. After repeated processing they are still unchanged and are in a qualitatively very good condition. The instruments were carefully and precisely processed.

These products passed the tests and are considered very good.

#### 3.2 Sterile container

After 10 process runs no changes in the material were observed. The containers are still in a qualitatively very good condition.

These products passed the tests and are considered very good.

### 4. Deviations / Recommendations

#### 4.1 No

instruments

#### 4.2 Sterile container

*In the visual inspection of the sterile container it was noticed that there was no article number on the products. **This means that these products cannot be matched***

with the manufacturer's instructions, It is therefore not possible to accurately identify and thus clearly allocate.

We recommend that, in the future, nopa implement this on all products.

## 5. Process parameters RDG

### Program P1: Instrumente

Program Time: 89 Min

Step 1	F1	M1	0°C	0			1Min	0°C	0		0Min
Step 2	F2	M3	25°C	0	D1	1.0ml/l	0Min	33°C	0		5Min
Step 3	F2	M4	35°C	0	D1	3.0ml/l	0Min	45°C	0	D1	3Min
Step 4	F2	MA	55°C	0			7Min	0°C	0		0Min
Step 5	F4	M4	0°C	0			1Min	0°C	0		0Min
Step 6	F9	M4	0°C	0			1Min	0°C	0		0Min
Step 7	FA	M4	93°C	0			0Min	93°C	0	D3	3Min
Step 8	F8	M5	130°C	0			6Min	100°C	0		10Min

### Program P3: Container

Program Time: 55 Min

Step 1	F1	M1	0°C	0			1Min	0°C	0		0Min
Step 2	F2	M4	45°C	0	D1	6.0ml/l	3Min	55°C	0		5Min
Step 3	F4	M4	0°C	0			1Min	0°C	0		0Min
Step 4	FB	M4	90°C	0			0Min	90°C	0		0Min
Step 5	F8	M5	130°C	0			6Min	100°C	0		8Min

#### Function: F

F0 = Inactivating Step (step is bypassed)  
 F1 = Pre-rinse (M1)  
 F2 = Cleaning (M3)  
 F3 = Neutralizing (M2)  
 F4 = Rinsing (M2)  
 F5 = Condensing (M6)  
 F6 = Chemical disinfecting (M4, M9)  
 F7 = Thermal disinfecting (M4, M9)  
 F8 = Drying (M5, M6, MB)  
 F9 = Clean rinsing (M4, M9)  
 FA = Thermal disinfecting A0=3000  
 FB = Thermal disinfecting A0=600  
 FC = Thermal disinfecting A0=60  
 FD = Final rinse (M4, M8, M9)  
 FE = Second rinse (M2, M4)  
 FF = Measure rinse  
 FG = Thermal disinfecting A0=3000 phase 2  
 FH = Thermal disinfecting A0=600 phase 2  
 FI = Thermal disinfecting A0=60 phase 2  
 FJ = Interval Rinse  
 FK = Measure Rinse K  
 FL = Measure Rinse L

#### Medium: M

M1 = Cold water  
 M2 = Warm water  
 M3 = Mixed water (warm + cold)  
 M4 = DI Water (fully de-calcified)  
 M5 = Drying (air)  
 M6 = Drying with condensing of exhaust air  
 M7 = Cold water over heat exchanger  
 M8 = Disinfected DI water (Boiler 55°C)  
 M9 = Pre-heated DI water (Boiler 95°C)  
 MA = Previous medium  
 MB = Air controlled  
 MC = Air non-vented

### [Program F1: Instruments

Program Time: 55 min

Step 1  
 Step 2  
 Step 3  
 Step 4  
 Step 5  
 Step 6  
 Step 7



Function: F

FO = Inactivating Step (step is bypassed)

F1 = Pre-rinse M1)

F2 = Cleaning (M3)

F3 = Neutralizing (M2) F4 = Rinsing (M2)

FS = Condensing (MS)

F6 = Chemical disinfecting (M4, M9)

F7 = Thermal disinfecting (M4, M9)

F8 = Drying (MS, M6, MB)

F9 = Clean rinsing (M4, M9)

FA = Thermal disinfecting A0=3000

FB = Thermal disinfecting A0=600

FC = Thermal disinfecting A0=60

FD = Final rinse (M4, M5, M9)

FE = Second rinse (M2, M4)

FF = Measure rinse

FG = Thermal disinfecting A0=3000 phase 2

FH = Thermal disinfecting A0=6000 phase 2

FI = Thermal disinfecting A0=60 phase 2

FJ = Interval Rinse

FK = Measure Rinse K

FL = Measure Rinse L

Medium: M

M1 = Cold water

M2 = Warm water

M3 = Mixed water (warm + cold)

M4 = DI Water (fully de-calcified)

M5 = Drying (air)

M6 = Drying with condensing of exhaust air

M7 = Cold water over heat exchanger

M8 = Disinfected DI water (Boiler 55°C)

M9 = Pre-heated DI water (Boiler 95°C)

MA = Previous medium

MB = Air controlled

MC = Air non-vented

## 6. Process parameter steam sterilization

Position

Step

Name

Duration

Date/time [Time]

Pressure [P11]

Temperature [T11]

Temperature [T21]

10 PREPARATION

30 EVACUATION

20 STEAM IMPACT

50 CURRENTS

30 EVACUATION

40 CURRENTS

20 STEAM IMPACT

30 EVACUATION

40 CURRENTS

20 STEAM IMPACT

30 EVACUATION

40 CURRENTS

20 STEAM IMPACT

30 EVACUATION

60 HEATING



70 STERILIZATION  
 90 PRESSURE DISCHARGE  
 100 DRYING  
 110 INTERVENTILATION  
 100 DRYING  
 110 INTERVENTILATION  
 100 DRYING  
 110 INTERVENTILATION  
 100 DRYING  
 110 INTERVENTILATION  
 100 DRYING  
 110 INTERVENTILATION  
 150 VENTILATION  
 160 DOOR SEAL RELEASE  
 170 RETRIEVAL

Position	Schritt	Schrittname	Dauer (s)	Datum/Zeit (Time)	Druck [P11]	Temperatur [T11]	Temperatur [T21]
0	10	VORBEREITEN	20	26.10.2015 12:48:11 000	949mbar	33.7°C	70.8°C
21	30	EVAKUIEREN	115	26.10.2015 12:48:31 000	954mbar	33.8°C	70.8°C
137	20	DAMPFSTOSS	10	26.10.2015 12:50:26 000	58mbar	54.2°C	70.0°C
148	50	STROMEN	62	26.10.2015 12:50:36 000	103mbar	52.8°C	69.9°C
210	30	EVAKUIEREN	32	26.10.2015 12:51:38 000	107mbar	64.3°C	69.9°C
242	40	STROMEN	12	26.10.2015 12:52:10 000	75mbar	59.7°C	69.7°C
254	20	DAMPFSTOSS	144	26.10.2015 12:52:22 000	71mbar	59.3°C	69.7°C
398	30	EVAKUIEREN	164	26.10.2015 12:54:46 000	1470mbar	111.1°C	111.2°C
563	40	STROMEN	63	26.10.2015 12:57:30 000	78mbar	41.6°C	55.3°C
627	20	DAMPFSTOSS	94	26.10.2015 12:58:33 000	91mbar	45.2°C	56.1°C
721	30	EVAKUIEREN	103	26.10.2015 13:00:07 000	983mbar	99.3°C	98.0°C
825	40	STROMEN	63	26.10.2015 13:01:50 000	78mbar	40.3°C	45.0°C
889	20	DAMPFSTOSS	182	26.10.2015 13:02:53 000	97mbar	47.0°C	51.8°C
1072	30	EVAKUIEREN	47	26.10.2015 13:05:55 000	1863mbar	118.3°C	118.3°C
1120	60	HEIZEN	285	26.10.2015 13:06:42 000	1004mbar	99.9°C	100.4°C
1405	70	STERILISATION	1083	26.10.2015 13:11:27 000	3113mbar	134.8°C	135.0°C
2490	90	DRUCKENTLASTEN	252	26.10.2015 13:29:30 000	3103mbar	134.9°C	134.7°C
2742	100	TROCKNEN	182	26.10.2015 13:33:42 000	63mbar	40.7°C	97.2°C
2924	110	ZWISCHENBELÜFTEN	179	26.10.2015 13:36:44 000	42mbar	60.3°C	94.7°C
3105	100	TROCKNEN	305	26.10.2015 13:39:43 000	957mbar	59.1°C	93.5°C
3410	110	ZWISCHENBELÜFTEN	180	26.10.2015 13:44:48 000	41mbar	75.8°C	93.1°C
3591	100	TROCKNEN	298	26.10.2015 13:47:48 000	954mbar	60.3°C	90.8°C
3890	110	ZWISCHENBELÜFTEN	180	26.10.2015 13:52:46 000	41mbar	71.7°C	88.7°C
4070	100	TROCKNEN	294	26.10.2015 13:55:46 000	951mbar	57.3°C	85.7°C
4364	110	ZWISCHENBELÜFTEN	179	26.10.2015 14:00:40 000	38mbar	67.7°C	83.2°C
4545	100	TROCKNEN	293	26.10.2015 14:03:39 000	949mbar	55.5°C	80.3°C
4838	110	ZWISCHENBELÜFTEN	180	26.10.2015 14:08:32 000	37mbar	67.3°C	77.9°C
5018	100	TROCKNEN	291	26.10.2015 14:11:32 000	949mbar	55.0°C	75.5°C
5310	110	ZWISCHENBELÜFTEN	139	26.10.2015 14:16:23 000	40mbar	66.8°C	73.4°C
5449	150	BELÜFTEN	1	26.10.2015 14:18:42 000	949mbar	56.8°C	71.5°C
5451	160	TÜRDICHTUNG ENTSPANN...	60	26.10.2015 14:18:43 000	949mbar	56.7°C	71.5°C
5512	170	ENTNEHMEN	0	26.10.2015 14:19:43 000	949mbar	54.2°C	71.0°C

## 7. Datasheets process chemistry

### Detergent for the preparation of thermostable and thermolabile instruments

#### Liquid concentrate

##### Area of application:

- Mechanical cleaning of thermostable and thermolabile instruments, including MIC and micro instruments, flexible endoscopes, anaesthetic equipment, containers and other medical devices
- Manual cleaning of thermostable and thermolabile instruments in immersion or ultrasonic bath
- Also suitable for manual and mechanical cleaning of da Vinci EndoWrist instruments

##### Performance spectrum:

- Reliably removes residues of dried-on and denatured blood
- Delivers a high depletion of organic matter and prevents the redeposition of protein residues
- Meets the current recommendations of the Robert Koch Institute (RKI) for the preparation of medical devices for minimizing the risk of transmission of variant Creutzfeldt Jakob disease (vCJD)
- Removes pathogenic prion proteins of different prion strains test, including the vCJD test strain to > 2 lg levels (1 %, 55 °C, 10 min)<sup>1</sup>
- Suitable for instruments and utensils made of stainless steel, tool steel, optics, conventional plastics and the materials of anaesthesia equipment
- Anodised aluminium must be tested for suitability

##### Special Features:

- Very good material protection
- Excellent cleaning performance due to the unique formulation based on alkalinity applicator, surfactants and enzymes
- When using manual pre-cleaning for subsequent automated preparation no rinsing of cleaning solution required
  - No neutralization step for machine preparation required, so short program sequences
  - No identifying marks: non-hazardous material, non-hazardous gas

##### Application and dosage:

neodisher MediClean forte can be used in washer disinfectors and in immersion and ultrasonic baths. The dosage, inter alia, depends on the usage area and the degree of contamination of the instruments. In the preparation of da Vinci EndoWrist instrument outputs neodisher MediClean forte is to be used for all manual pre-cleaning stages, ultrasonic pretreatment and for the automated reprocessing process. The following parameters are recommended when using neodisher MediClean forte:

- Mechanical cleaning of thermostable and thermolabile instruments
- Mechanical cleaning of flexible endoscopes and endoscopic accessories
- Mechanical cleaning of da Vinci EndoWrist- Instruments
- Manual cleaning of thermostable and thermolabile instruments in immersion and ultrasonic bath
- Manual cleaning of flexible endoscopes and endoscopic accessories in immersion and ultrasonic bath
- Manual cleaning of da Vinci EndoWrist- Instruments in immersion and ultrasonic bath

\* The dosage depends on the degree of staining

\*\* depends on the recommendation of the cleaning and disinfection equipment manufacturer

Dosing devices suitable for the dosage are to be used.

In the cleaning step, and in the final rinse it is recommended to use demineralized water. When using classical alkaline cleaners the required neutralization step can be omitted. For the processing of eye instruments, an additional intermediate rinsing with water is recommended before the final rinse.

The application solution for manual cleaning has to be repeated at least every working day and changed if contamination is visible.

#### General information on use:

- For professional use only.
- Do not mix with other products.
- Flush suction hose with water before including in the product change dosing system.
- The preparation must be performed with appropriate procedures according to the RKI guideline and the Medical Devices Directive.
- The neodisher MediClean forte-solution must be fully rinsed with water (preferably deionized water).
- Please observe the preparation recommendations of the instrument manufacturer in accordance with the requirements of DIN EN ISO 17664.
- The operating instructions of the cleaning and disinfection equipment manufacturer must be followed.

#### Expert report:

We can make the process expert report for the preparation of da Vinci instruments available upon request.

#### Technical data:

The PH value	10.4 -10.8 (2 - 10 ml/l, determined in deionized water, 20 °C), can differ in city or softened water as well as, for example, due to pre-rinsing.
Density	1.1 g/cm <sup>3</sup> (20 °C)
Viscosity	<10 mPa s (concentrate, 20 °C)
Titration factor	0.78 (according to neodisher MediClean forte titration method)

#### Ingredients:

Ingredients for detergents according to EC Detergents Regulation 648/2004:

< 5 % nonionic and anionic surfactants also include: Enzymes

#### EC marking:

neodisher MediClean forte fulfils the requirements of Directive 93/42 / EEC, Appendix I concerning medical devices.

#### Storage information:

Store cool but frost-free. Always store at a temperature between 0 and 25 °C. Storable for 2 years if kept in an appropriate storage place.

EXP: see imprint on the label after the symbol

#### Warning and Safety Instructions:

neodisher MediClean forte is not a harmful substance according to the Dangerous Preparations Directive 99/45/EC.

Only dispose of the container when it is empty and closed. Disposal of product residues: see MSDS.

For further safety information see EC safety data sheets. These are found at [www.drweigert.de](http://www.drweigert.de) under the heading "Service".

Status 01/2014

The data contained herein are based on our current knowledge and experience. These do not release the user from own examinations and tests. No legally binding guarantee of certain properties can be derived therefrom.

**neodisher® MediKlar special** rinsing agent for the automated reprocessing of thermostable and thermolabile instruments liquid concentrate

Main fields of application:

Rinsing of medical devices such as surgical instruments incl. eye instruments, anaesthesia utensils. Instrument containers, implants and baby bottles in washer disinfectors.

Rinsing of bedsteads in large room decontamination systems that can be machine-processed according to manufacturer instructions.

Characteristics:

neodisher MediKlar special

- supports drying due to its very good wetting properties, even on difficult to wet plastic surfaces
- shortens drying time significantly
- neutralizes alkali residues
- reduces staining by using softened water in the final rinse

Stress cracking may occur in components of anaesthesia equipment made of Potysulfon (PSU) and Polyphenylene (PPSU) such as connectors of laryngeal masks, valves, adapters and parts of instrument container lids in contact with production-required rinsing. They are each tested for suitability.

Application and dosage:

neodisher MediKlar special is used in washer disinfectors and large room decontamination systems. The dosage is, inter alia, dependent on usage scope and water quality. The following parameters must be observed when using neodisher MediKlar special:

- For rinsing surgical instruments, anaesthesia equipment, instrument containers, implants and baby bottles:  
0.2 - 0.4 ml/l
- For rinsing bedsteads:  
0.2 - 0.8 ml /l

To avoid water spots, it is recommended that demineralized water be used in the final rinse.

Machines and dosing must be suitable for the use of neodisher MediKlar special.

Flush suction hose with water before including in product change dosing system.

Do not mix with other products.

The preparation must be performed with appropriate procedures in accordance with the RKI guideline and the Medical Devices Directive.

Please note the processing recommendations of the instrument manufacturer in accordance with the requirements of DIN EN ISO 17664, the preparation recommendations of the manufacturer of the bedsteads as well as the recommendations of the Working Group for Bedsteads and Trolley Decontamination Systems (AK-BWA) [Arbeitskreises Bettgestell- und Wagendekontaminationsanlagen] in the current issue of the AK-BWA brochure "Mechanical Decontamination" ,

The operating instructions of the machine manufacturer must be observed.

For professional use only.

Technical data:

Density (20 °C): 1.05 g/cm<sup>3</sup>

pH range (measured in deionized water, 20 °C) 0.2-0.8ml /l: 4.0 to 3.5 Viscosity (concentrate, 20 °C): < 50 mPa s

**Ingredients:**

Ingredients for detergents according to EC Detergents Regulation 648/2004:

< 5 % phosphonates,

15-30 % nonionic surfactants,

including preservatives (Methylchloroisothiazolinone / Methylisothiazolinone)

EC-marking: neodisher MediKlar special meets the requirements of Directive 93/42/EEC, Appendix I concerning medical devices.

Storage information: Store in a place free from frost. Always store at a temperature between 0 and 30 °C.

Storable for 3 years if kept in an appropriate storage place. EXP: see imprint on the label after the

hazard warnings symbol and safety advice: neodisher MediKlar special is not a harmful substance according to the Dangerous Preparations Directive 99/45/EC.

Only dispose of the container when it is empty and closed. Disposal of product residues: see MSDS.

For further safety information see EC safety data sheets. These are found at [www.drweigert.de](http://www.drweigert.de) under the heading "Service".



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Die Angaben dieses Merkblattes beruhen auf unseren derzeitigen Kenntnissen und Erfahrungen. Sie befreien den Verwender nicht von eigenen Prüfungen und Versuchen. Eine rechtlich verbindliche Zusicherung bestimmter Eigenschaften kann hieraus nicht abgeleitet werden.

With the above information, which is appropriate to our current knowledge we describe our product regarding possible safety necessities, but we do not involve any quality description or promise certain properties.

**neodisher® IR****Liquid acid basic cleaning agent for use in immersion bath**

Main fields of application: Basic cleaning agent for stainless steel surgical instruments in immersion and ultrasonic bath. The basic cleaning should only be used for hardened chrome steel instruments and stainless steel instruments.

Characteristics: neodisher IR is a special product for removing tarnish, rust film and extraneous rust. Stubborn mineral deposits, which may result from various errors in the preparation such as inappropriate water and steriliser steam qualities, will be automatically removed with neodisher IR. Instruments of uncured chrome steel, carbon steel, alloy or other acid sensitive materials should not be treated with neodisher IR. This also applies to chrome and nickel-plated instruments. For instruments made of stainless steel, which have no guarantee of quality, a preliminary test for suitability must be performed. Instruments with tungsten carbide inserts are suitable for thorough cleaning, as long as the restrictions mentioned in the instructions of the instrument manufacturer<sup>1</sup> are observed. A brightening of the label can be performed with laser marked instruments.

The basic cleaning with neodisher IR is not suitable for a first cleaning of brand-new instruments.

The container for performing the basic cleaning, just like the drain pipelines through which the neodisher IR solutions are discharged, must be made of acid-resistant material (Eternit and cast-iron pipes are not suitable). Optionally, the usage solution of neodisher IR can be neutralized with an alkaline cleaning agent (without active chlorine) before being discharged.

Application and dosage: Only for instruments made of hardened chrome steel or chrome-nickel steel!

**Basic cleaning in immersion bath:**

Load instruments in 1 -10 % strength warm neodisher IR-solutions (10 - 100 ml /l, max 50 °C.). For instruments with tungsten carbide inserts only use 1 - 3 % neodisher IR solution (30 ml /L 10). After an exposure time of about 1 hour, rinse instruments thoroughly with water and dry them. Instruments with currently perfect appearance will be supplied for further preparation.

**Basic cleaning in an ultrasonic bath:**

Load instruments in 1.5 - 3.5 % strength warm neodisher IR-solutions (15 - 35 ml /l, max 50 °C.).

The reaction time, according to the device manufacturer, is between 1-5 min. Should spots and discolouration not be properly removed (discolouration may build up over a long period of time) repeat basic cleaning. With basic cleaning in immersion bath it is possible to extend the residence time up to 4 hours. In no case should the instruments remain unmonitored in the solutions overnight.

If, even after this immersion cleaning, the discolouration does not disappear, the Application Technology Department must be consulted, in order to examine the nature of the discolouration and decide on a special method for removal. In any event, an attempt should be made to determine the causes, and to remedy these as soon as possible.

Treatment with metal brushes must be avoided, since the stainless steel surfaces are irreversibly damaged by this treatment, and thus are more susceptible to corrosion.

The neodisher IR-solution must be completely rinsed off with water (preferably deionized water). Do not mix with other products.

The preparation must be performed with appropriate procedures in accordance with the RKI guideline and the Medical Devices Directive.

For professional use only.



Technical data: Density (20 °C): 1.4 g/cm<sup>3</sup>

pH range (determined in deionized water, 20 °C) 1 -10% strength (10 -100 ml /L): 1.8 to 0.9 Viscosity (concentrate, 20 °C): <50 mPas

Titration factor: 0.19 (in accordance with neodisher titration method)

Ingredients: Ingredients for detergents according to EC Detergents Regulation 648/2004:

< 5% non-ionic surfactants > 30% phosphates

EC-marking: neodisher IR meets the requirements for medical devices according to Directive 93/42/EEC.

Storage information: Avoid temperatures below -15 °C. Usable for 4 years if kept in appropriate storage.

Warning and Safety Instructions: For safety and environment information, refer to the EC safety data sheets. These are found at [www.drweigert.de](http://www.drweigert.de) under the heading "Service".

Only dispose of the container when it is empty and closed. Disposal of product residues: see MSDS.



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Die Angaben dieses Merkblattes beruhen auf unseren derzeitigen Kenntnissen und Erfahrungen. Sie befreien den Verwender nicht von eigenen Prüfungen und Versuchen. Eine rechtlich verbindliche Zusicherung bestimmter Eigenschaften kann hieraus nicht abgeleitet werden.

With the above information, which is appropriate to our current knowledge we describe our product regarding possible safety necessities, but we do not involve any quality description or promise certain properties.