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ilac-MRA DAkkS Deutsche Akkreditierungsstelle D-PL-18818-02-01 D-PL-18818-02-02

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten ZLG-AP-314.10.23

2019-06-11

TEST REPORT

Sample id number:	SN 27587
Test number:	2019-1205 2019-1206 2019-1207
Date of order:	2019-05-02
Date of delivery:	2019-05-06
Test sample:	Anpassungsring-Set (4 Ringe ohne Innendraht), SET R GROSS, Charge: K 27/18/1 Anpassungsring-Set (4 Ringe ohne Innendraht), SET R MITTEL, Charge: K 32/19/1
Client:	Dr. Arabin GmbH & Co. KG
Test period:	2019-05-14 – 2019-05-24
Test methods:	Reprocessing of health care products - Information to be provided by the medical device manufacturer. Information to be provided by the medical device manufacturer for the reprocessing of medical devices "EN ISO 17664, SOP 19-001 Soiling of products with test soils for testing cleaning and disinfection and recovery of test soils following DIN ISO TS 15883-5, SOP 19-002 Sterilization of medical devices - Moist heat Part 1: Requirements for the development, validation and routine control of sterilization processes for medical devices EN ISO 17665-1, SOP 19-003 Robert Koch Institute guideline "Hygiene requirements for the reprocessing of medical devices."

Overview over the test samples

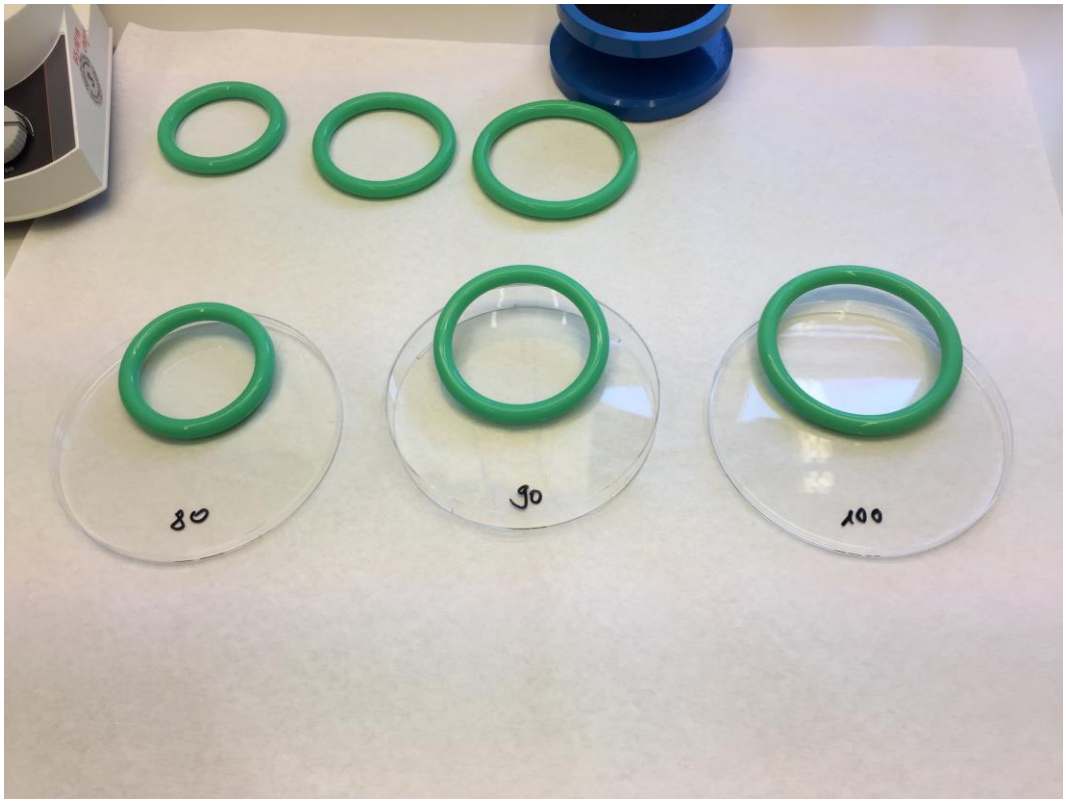

Fig. 1: Anpassungsring-Set, 2 Ringe Größe 80, 2 Ringe Größe 90, 2 Ringe Größe 100

Multiple reprocessing

The products were reprocessed 5 times with the procedures to be tested (cleaning and disinfection in the WD and sterilization in the fractionated vacuum process) before being used for testing.

Contamination of the test samples with test soil according to DIN ISO TS 15883-5: 2006; (SOP 19-002)

Tests of the automated cleanability and disinfectability

Date of contamination: 2019-05-14

Individual components of the test soil:

Test sample:	Anpassungsring-Set (4 Ringe ohne Innendraht), SET R GROSS, Charge: K 27/18/1 Anpassungsring-Set (4 Ringe ohne Innendraht), SET R MITTEL, Charge: K 32/19/1
Test soil 1 (cleanability):	Heparinized sheep blood diluted 1:5 with 0.85% NaCl, reactivated with protamine, charge 31418500/01, Fa. Fiebig Nährstofftechnik
Test soil 2 (disinfectability):	Heparinized sheep blood diluted 1:5 with 0.85% NaCl, reactivated with protamine, charge 31418500/01, Fa. Fiebig Nährstofftechnik with the test germ *E. faecium* ATCC 6057.
Preparation of the test soil 2 (disinfectability):	The 2nd passage of Enterococcus faecium cultured on BHI agar (Brain-Heart Infusion Agar) was adjusted to 1.5 - 5.0 x 109 CFU/ml in dilution solution (0.85% NaCl, 0.1% tryptone). After centrifugation, the dilution solution was decanted, and the volume was replenished with heparinized blood. After careful homogenization of the suspension with glass beads, protamine was added immediately before use.
Contamination of the test samples:	500µl test soil were pipetted into the glove and distributed.
Drying of the test soil:	1h at 22 ± 1°C

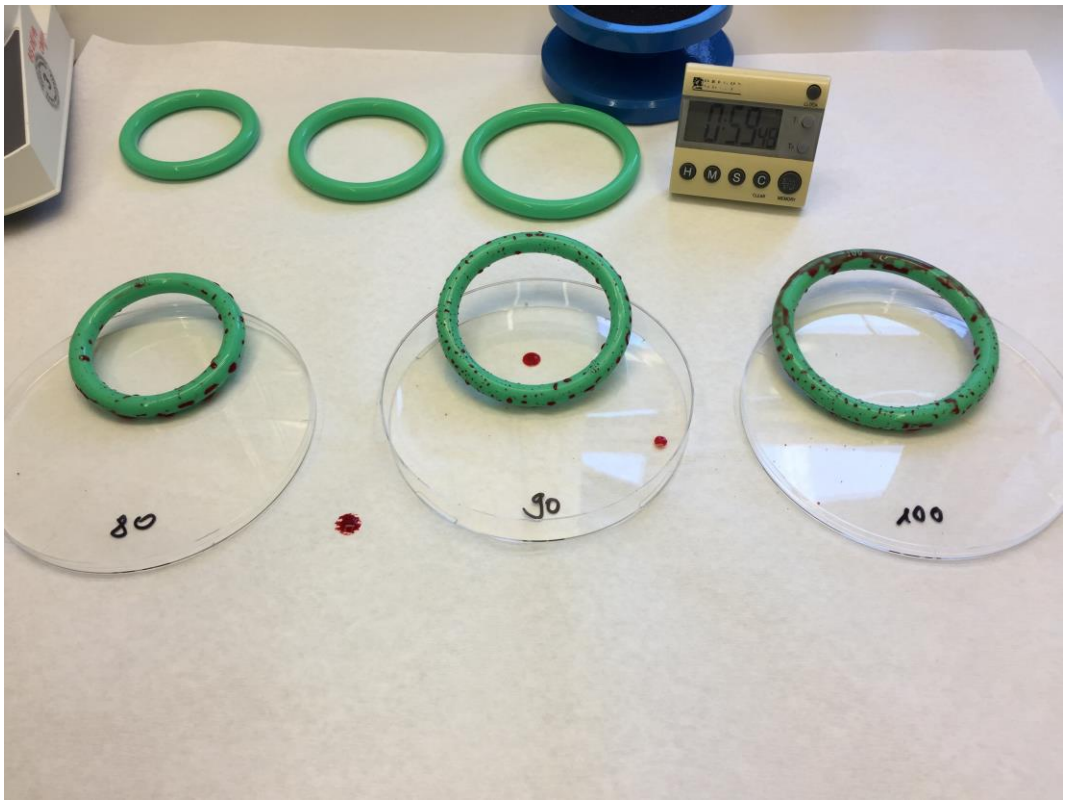

Fig. 2: Contaminated test samples

Carrying out the cleaning of the test samples

Date of the test:	2017-07-19
Cleaning and disinfection device:	Miele PG8581, serial-no.: 00/018417797
Program:	Program 2 Vario TD dental (only cleaning steps) Step 1 Pre-clean with cold tap water Step 2 Clean 0.5% cleaner at 55°C for 5 minutes with demineralized water Drain Step 3 Rinse with demineralized water for 1 minute **To test the cleanability, the reprocessing process was stopped after the intermediate rinse immediately before the disinfection step.**
Cleaning:	Chemo-thermal with alkaline cleaner
Cleaner:	0.5 % Dr. Weigert neodisher Medi® Clean Forte, LOT: 589397/0118, MHD 2020-01
Application:	Reprocessing was carried in instrument sieves
Replicates:	In each case, 3 test specimens were prepared.
Temperature control:	The control of the temperature were registered with data loggers of the company Microsensys.
Acceptance criteria:	According to guideline of DGKH, DGSV and AKI (2017); residual protein per test sample. Limit value: ≥ 150 µg / instrument Warning value: > 80 - 150 µg / instrument Guideline value: ≤ 80 µg / instrument

Fig. 3: Used cleaning and disinfection device

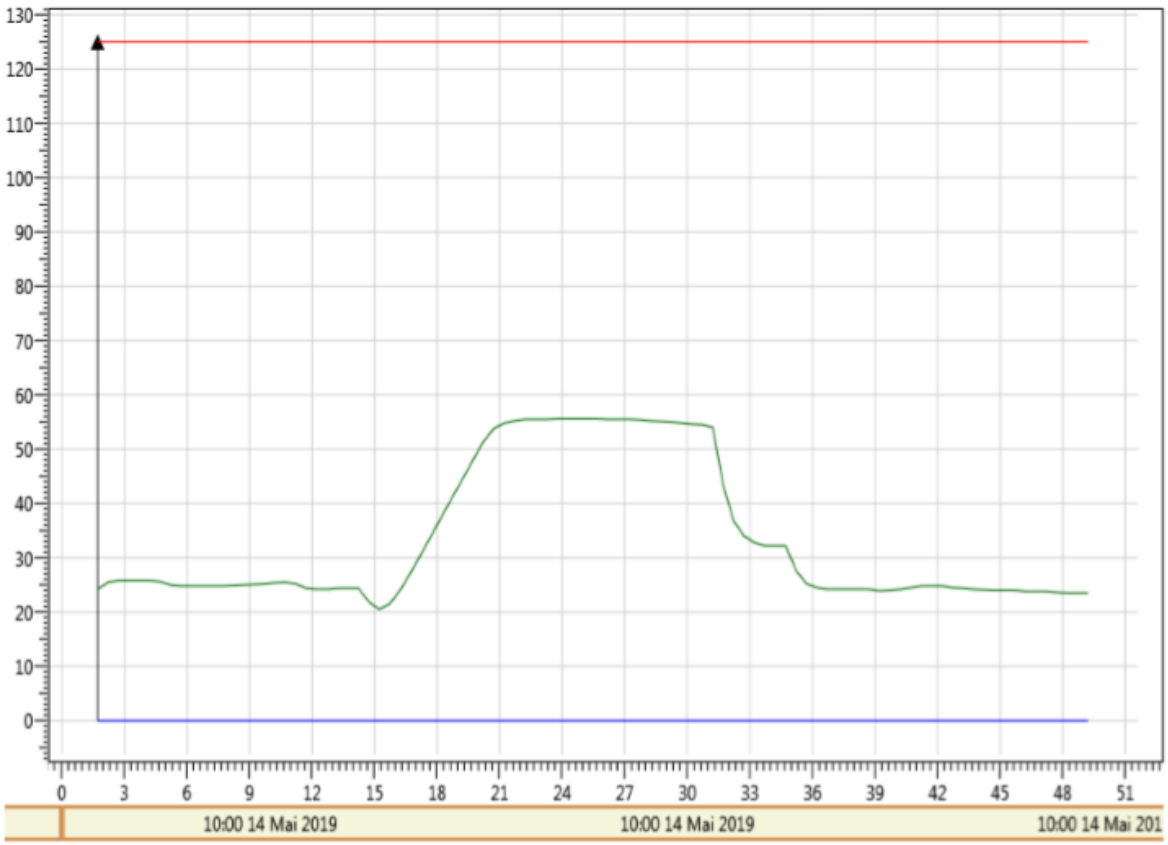

Fig. 4: Temperature profile cleaning run

Elution of the reprocessed test samples according to DIN ISO TS 15883-5:2006; (SOP 19-002)

Elution of the test samples, contaminated with reactivated heparinized blood (cleaning)

To test the cleanability, the reprocessing process was stopped after the intermediate rinse immediately before the disinfection step.

Date of elution:	2019-05-14
Elution solution:	1% SDS (sodiumdodecylsulfat)
Elution volume:	5ml
Elution of the test samples	
Test samples:	Anpassungsring-Set (4 Ringe ohne Innendraht), SET R GROSS, Charge: K 27/18/1 Anpassungsring-Set (4 Ringe ohne Innendraht), SET R MITTEL, Charge: K 32/19/1
Description of the elution:	Test samples eluted in 5 ml 1% SDS in a stomacher bag.
Proteinanalysis:	Modified OPA-method (SDS-eluate)

Results for protein analysis using the modified OPA method (SOP 17-008)

Proteinanalysis: Modified OPA-method (SDS-eluate)

Test time period: 2019-05-14

Results for the positive controls

Control	Volume SDS-solution [ml]	Dilution factor	Extinction	Protein-concentration [µg BSA/TS]
TS 80	5	1:5	0.314	**2804.00**
TS 90	5	1:5	0.244	**2178.91**
TS 100	5	1:5	0.276	**2464.67**

Results of the test samples

Sample	Volume SDS-solution [ml]	Dilution factor	Extinction	Protein-concentration [µg BSA/TS]	Depletion [%]	Criteria
Ring 80	5	1	0.000	**n.d.**	≥99.99	Pass
Ring 90	5	1	0.000	**n.d.**	≥99.99	Pass
Ring 100	5	1	0.009	**16.07**	99.35	Pass

Legend:
OPA = o-phtaldialdehyde
TS = Test sample
Depletion [%] = 100-(Residual contamination / initial load *100)
BSA = Bovine Serum Albumin

Specifications for reprocessed instruments according to guideline DGKH, DGSV, AKI, October 2017

Limit value: > 150µg / test specimen
Warning value: > 80 - ≤ 150 µg / test specimen
Guideline value: ≤ 80µg / test specimen

Carrying out the cleaning and disinfection of the test samples

Date of the test:	2019-05-14
Cleaning and disinfection device:	Miele PG8581, serial-no.: 00/018417797
Program:	Program 2 Vario TD dental (only cleaning steps) Step 1 Pre-cleaning with cold tap water Step 2 Cleaning 0.5% detergent at 55°C for 5 minutes with demineralized water Step 3 Rinsing with demineralized water for 1 minute Step 4 Thermal disinfection with demineralized water at 93°C for 5 minutes
Cleaning:	Chemo-thermal with alkaline cleaner
Disinfection:	Thermodesinfection 93°C, holding time 5 min
Cleaner:	0.5 % Dr. Weigert neodisher Medi® Clean Forte, LOT: 589397/0118, MHD 2020-01
Application:	Reprocessing was carried in instrument sieves
Replicates:	In each case, 3 test specimens were prepared.
Temperature control:	The control of the temperature were registered with data loggers of the company Microsensys.
Acceptance criteria:	Visually clean and reduction of test bacteria by > 5 log steps

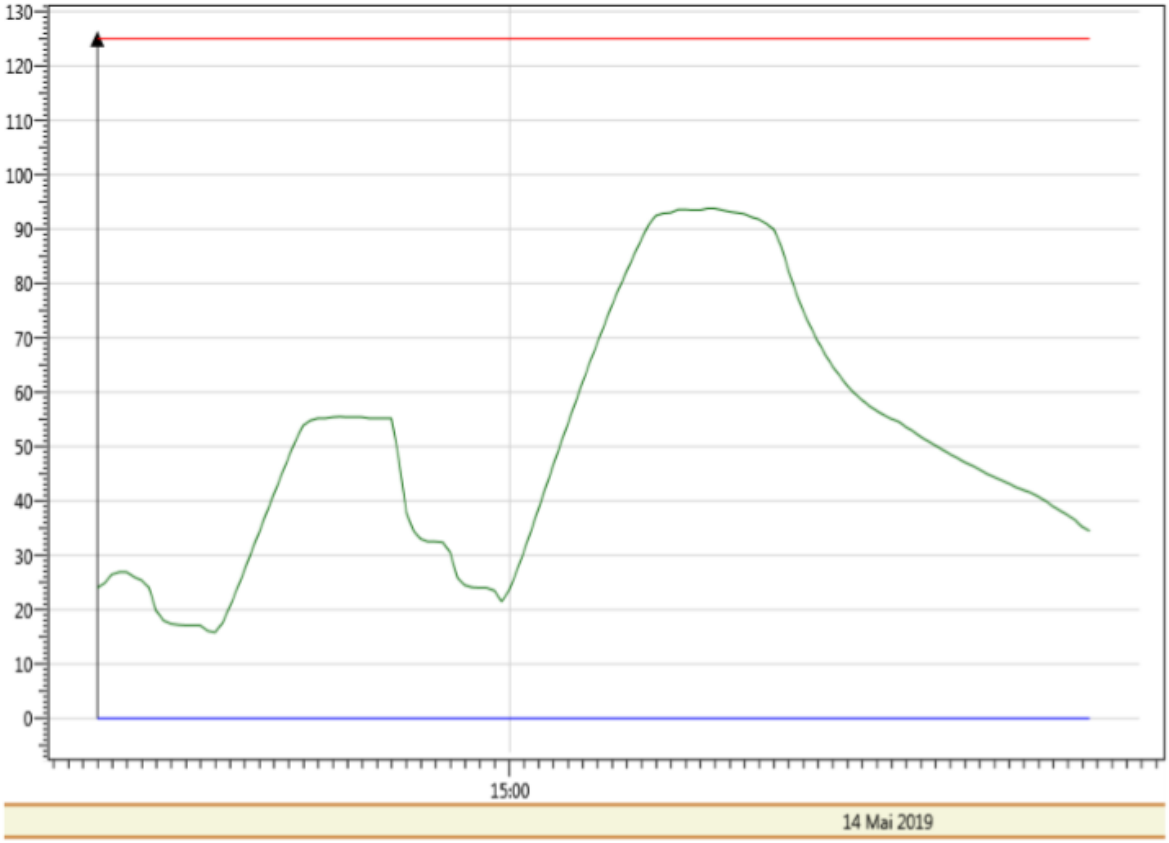

Fig. 5: Temperature profile cleaning and disinfection

Elution of the reprocessed test samples according to DIN ISO TS 15883-5:2006; (SOP 19-002)

Elution of the test samples, contaminated with reactivated heparinized blood and the test germ *E. faecium* (disinfection)

Date of elution:	14.05.2019
Elution solution:	TSB (Tryptic Soya Broth)
Elution volume:	10ml TSB

Elution of the test samples

Test samples:	Anpassungsring-Set (4 Ringe ohne Innendraht), SET R GROSS, Charge: K 27/18/1 Anpassungsring-Set (4 Ringe ohne Innendraht), SET R MITTEL, Charge: K 32/19/1
Description of the elution:	Test sample eluted in 10ml TSB in stomacher bag.

Cultivation of the elution solution

Positive controls of the test samples:	With dilution solution (0.1% tryptone and 0.85% sodiumchloride) dilutions were prepared and spread on TSA (trypticase soya agar).
Test samples:	1.0 and 0.1ml of the eluate was spread on TSA
Incubation:	Cultivation on TSB 7d at 36 ± 1°C Incubation of the eluates 7d at 36 ± 1°C Subcultivation of the eluates on SBA 24h at 36 ± 1°C
Calculation:	Calculation of the reduction factor (RF) $RF = \log_{cfu/positive\ control} - \log_{cfu\ test\ piece}$

Results of the thermal disinfection performance test according to EN ISO 15883-4: 2009 and ISO/TS 15883-5; (SOP 30-001)

Test time period: 2019-05-14 – 2019-05-21

Cleaning and disinfection device: Miele PG8581, serial-no.: 00/018417797

Program Program 2 Vario TD dental (only cleaning steps)

Cleaning: Chemo-thermal with alkaline cleaner

Disinfection: Thermodesinfection 93°C, holding time 5 min

Cleaner: 0.5 % Dr. Weigert neodisher Medi® Clean Forte, LOT: 589397/0118, MHD 2020-01

Results of the positive controls

Recovery of *E. faecium*

Control	Volume TSB [ml]	CFU/TS	CFU log/TS
TS 80	10	3.04×10^9	**9.04**
TS 90	10	3.03×10^9	**9.03**
TS 100	10	2.95×10^8	**8.95**

Results of the test samples after disinfection

Recovery of *E. faecium*

Sample	Volume TSB [ml]	CFU/TS	Enrich-ment*	log/TS	RF	Criteria
Ring 80	10	0	-	0.00	**≥9.04**	**Pass**
Ring 90	10	0	-	0.00	**≥9.03**	**Pass**
Ring 100	10	0	-	0.00	**≥8.95**	**Pass**

Legend:
*) = Subcultivation on TSA after 7 days
CFU = Colony forming units
TS = Test sample
TSA = Tryptic Soya Agar
TSB = Tryptic Soya Broth
\+ = Turbidity due to the growth of bacteria in the subcultivation (enrichment).
\- = absence of turbidity as a result of no growth of germs
RF = Reduction factor = (initial contamination [log] – residual contamination [log]

Contamination of the test samples according to EN ISO 15883-1: 2006; SOP 19-001

Date of contamination: 2019-05-15

Individual components of the test soil:

Test soil: Spore suspension of *Geobacillus stearothermophilus* ATCC 7953, Fa. Crosstex, Charge AR546, stable until 02-2020

Contamination of the test samples according to SOP 19-001

Test samples: Anpassungsring-Set (4 Ringe ohne Innendraht), SET R GROSS, Charge: K 27/18/1
Anpassungsring-Set (4 Ringe ohne Innendraht), SET R MITTEL, Charge: K 32/19/1

Contamination of the test samples:

Contamination of the test samples: 100 µl test soil was distributed on the fitting ring.

Drying of the test samples: 1h drying at room temperature (22 ±2°C, 40 ±5% relative humidity)

Packaging: Paper/laminate film Stericlin Sterifoil

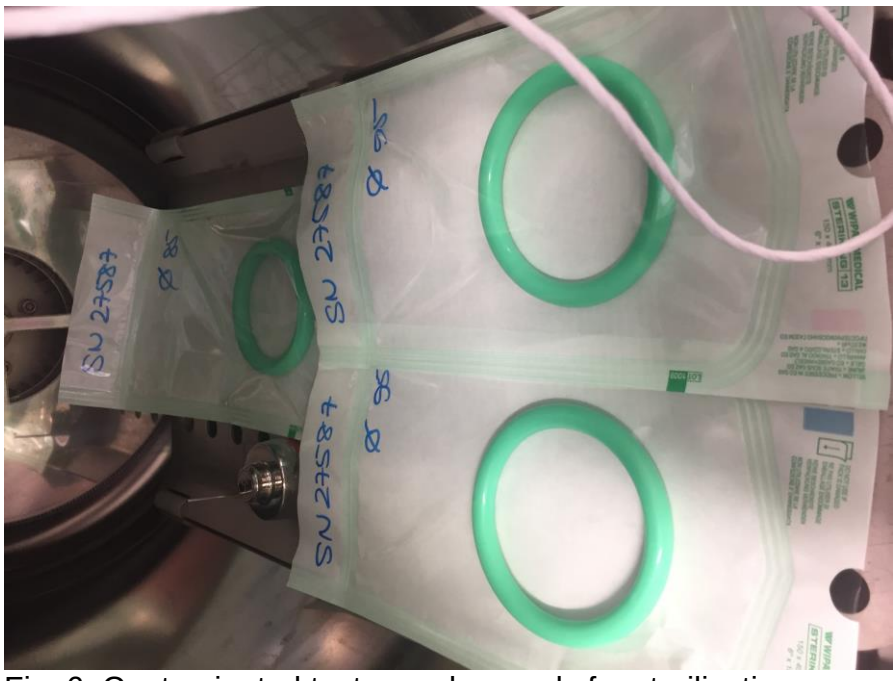

Fig. 6: Contaminated test samples ready for sterilization

Sterilization of the test sample

Date of test:	2019-05-15
Sterilizer:	Systec DX-45 SN D 3986
Packaging:	Paper/laminate film Stericlin Sterifoil
Sterilization process:	134 °C, 5 min holding time, fractionated vacuum process
Positive controls:	Colony forming units (CFU) of the contaminated but unexposed instrument were determined from each batch.
Replicates:	3 test samples

Fig. 7: Autoclave used Systec DX-45

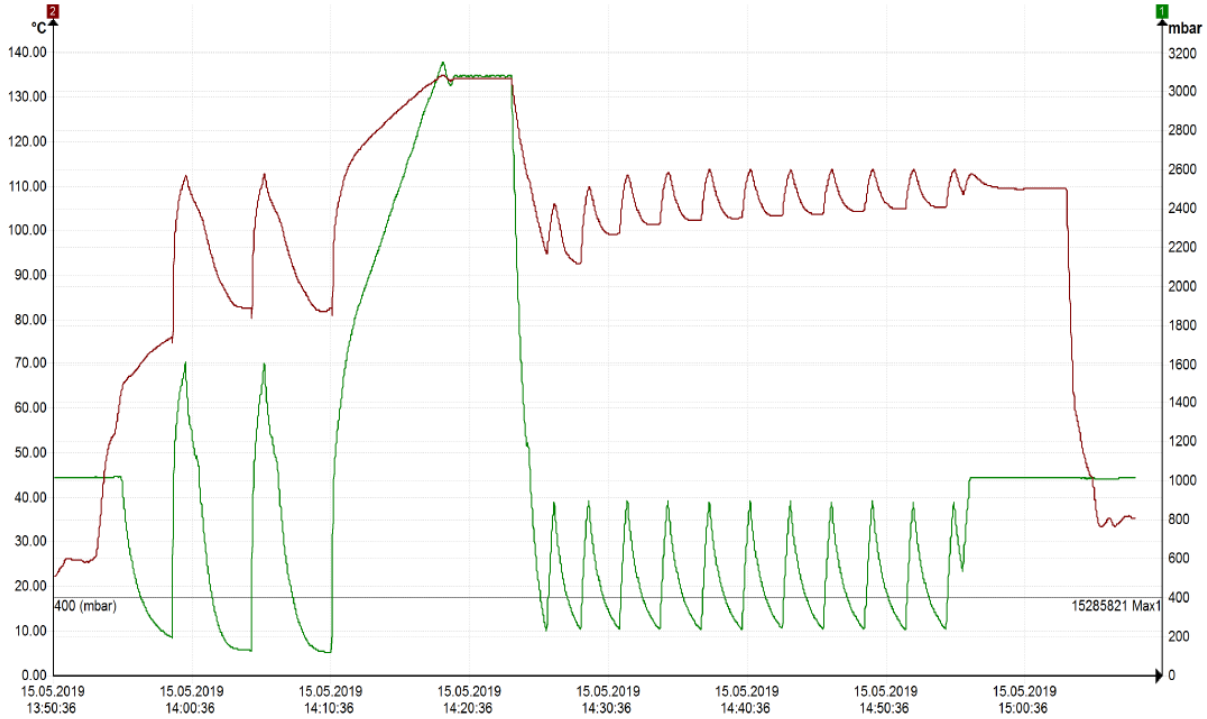

Fig. 8: Temperature profile sterilization (134 °C, 5 min holding time, fractionated vacuum process)

Elution of the test sampels

Date of elution:	2019-05-19
Elution solution:	TSB (Tryptic Soya Broth)
Elution volume:	10ml TSB
Discription of the elution:	The surfaces of the test samples were eluted with 10 ml of elution solution in stomacher bags.

Cultivation of the elution solution

Positive controls of the test samples:	With dilution solution (0.1% tryptone and 0.85% sodiumchloride) dilutions were prepared and spread on TSA (trypticase soya agar).
Test samples	1.0 and 0.1ml of the eluate was spread on TSA
Incubation:	Cultivation on TSB 7d at 36 ± 1°C Incubation of the eluates 7d at 36 ± 1°C Subcultivation of the eluates on TSA 24h at 55 ± 1°C
Calculation:	Calculation of the reduction factor (RF) $RF = \log_{cfu/positive\ control} - \log_{cfu\ test\ piece}$
Acceptance criteria:	Reduction of the test germ (*G. stearothermophilus* spores) by > 6 log steps, no germ growth after sterilization.

Results of the sterilization according to EN ISO 17664; SOP 19-003

Test time period: 2019-05-15 until 2019-05-22

Contamination: Spore suspension of *Geobacillus stearothermophilus*

Packaging: Paper/laminate film Stericlin Sterifoil

Sterilizer: Systec DX-45 SN D 3986

Program: 134 °C, 5 min holding time, fractionated vacuum process

Results of the positive controls

Control	Instrument	Culture medium	CFU/TS	log/TS
TS	Ring 80	TSA	2.41×10^6	**6.41**
TS	Ring 90		2.45×10^6	**6.45**
TS	Ring 100		2.48×10^6	**6.48**

Results of the test samples after elution (134°C, 5 min.)

Sample	Instrument	Cycle	Culture medium	CFU/TS	Enrich-ment	log/TS	RF [log]	Criteria
TS1	Ring 80	1	TSA	0.00	-	0.00	≥6.41	**Pass**
TS2	Ring 90	1		0.00	-	0.00	≥6.45	**Pass**
TS3	Ring 100	1		0.00	-	0.00	≥6.48	**Pass**

Legend:
*) = Subcultivation on TSA after 7 days
CFU = Colony forming units
TS = Test sample
TSA = Tryptic Soya Agar
TSB = Tryptic Soya Broth
\+ = Turbidity due to the growth of bacteria in the subcultivation (enrichment).
\- = absence of turbidity as a result of no growth of germs
RF = Reduction factor = (initial contamination [log] – residual contamination [log]

Summary of the results

Cleaning and disinfection
The tests performed demonstrated that quantifiable cleaning and disinfection of the fitting ring set (4 rings without inner wire), SET R GROSS, batch: K 27/18/1, fitting ring set (4 rings without inner wire), SET R MEDIUM, batch: K 32/19/1 in a washer-disinfector is possible.

The cleaning of the products in a chemo-thermal process resulted in a removal of > 99% of the test soiling. The requirements of the DGKH, DGSV and AKI guidelines were met. Each of the instruments had a residual protein value of < 80µg after reprocessing.

The results of the disinfection show that the required reduction of the test germ by ≥ 5 lg steps could be achieved with the procedure performed.

Sterilization
The sterilization of the product fitting ring set (4 rings without inner wire), SET R LARGE, batch: K 27/18/1, fitting ring set (4 rings without inner wire), SET R MEDIUM, batch: K 32/19/1 in paper / laminate film was performed using an autoclave with fractionated pre-vacuum process.

At a temperature of 134°C and 5min holding time, the required reduction of spores of *G. stearothermophilus* of more than 6 lg steps was detected.

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Dr. med. univ. S. Werner
Head of Scientific-Technical Affairs
Medical Devices

DocuSigned by:
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Dr. rer. nat. O. Riebe
Division Manager
Reprocessing of Medical Devices

Annex to test report SN 27587

Certificate of the spore suspensension

Charge: 29 3.18 2
EWE: 9,22 log 1ml

CROSSTEX A CANTEL MEDICAL COMPANY | PROTECTS

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Spore Suspension

PRODUCT CODE: VGS-108H

QUANTITY: 10 mL each vial, 20% Ethanol Solution

ORGANISM: *Geobacillus stearothermophilus*, ATCC® 7953

FOR USE IN MONITORING: Plasma/Vaporized Hydrogen Peroxide

This lot of product meets, where applicable, the accepted performance criteria recommended in the USP and ISO 11138-1.

LOT	AR546	2020-02-29(YYYY-MM-DD)	POPULATION[1]:	1.8×10^6/0.1mL

Performance Characteristics		
PROCESS	PARAMETERS	*D*-VALUE[2]
Vaporized Hydrogen Peroxide	2.3 mg/L ± 0.4 mg/L, 50°C ± 0.5°C	1.5 minutes

[1]After a preliminary heat treatment of 95-100ºC for 15 minutes

[2]Determined using fraction negative procedures (e.g. Stumbo-Murphy-Cochran) in an AAMI/ISO compliant test vessel. The *D*-value is reproducible only under the exact conditions under which it was determined. Users may not necessarily obtain the same results.

Storage and Shelf Life

+8°C / +2°C	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
Shelf-life	24 Months from the date of manufacture.		
	Do not used damaged vials of Spore Suspension. Do not use after expiration date. Spore Suspensions contain live cultures and should be handled with care.		

Dispose: Autoclave for not less than 30 minutes at 121ºC or per other validated disposal cycle prior to discard.

Kristin Crandall 3/7/2018
QUALITY ASSURANCE APPROVAL

Mfg. By: **Crosstex International, Inc.**
6789 W. Henrietta Road • Rush, NY 14543 USA • (800) 860-1888 • Fax: (419) 666-1715 • www.SterilizationProducts.com

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