Validation Report

Test description	Test report no.	205005
	Description	Validation of a sterilization process for medical devices to fulfil the requirements of Council Directive 93/42/EEC annex 1, clause 13.6 concerning medical devices and DIN EN ISO 17664:2004-07, chapters 4.1 and 4.2.
	Date of receipt	2020-03-05 (yyyy-mm-dd)
	Processing time	2020-03-18 - 2020-03-25 (yyyy-mm-dd)
	Date of issue	2020-03-27 (yyyy-mm-dd)
Order	Customer	Order number: Your order from Feb. 28th, 2020
	SAL	Order number: 202159
Customer	Address	DENLUX A/S – Dental Electronic A/S Metalbuen 38 2750 Ballerup DENMARK
Test laboratory	Address of record	SAL GmbH Feldstrasse 14 61479 Glashuetten GERMANY
	Address laboratory	SAL GmbH Auf der Lind 10 65529 Waldems Esch GERMANY
Sample	Description	Pulppen B1000/DP2000/DP3000 Electrodes and Conductive rubber tips
	Item number	Electrode, Angled Type (Part No. K10030) Electrode, Straight Type (Part No. K10029) Rubber tip (Part No. K10031)
	Picture	 

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Table of contents

Annex

1 Certificates (DAkkS, ZLG)
2 Calibration certificates
3 Biological indicator certificates
4 Results of sterility testing
5 Sterilization process data of run 1 of 3
6 Sterilization process data of run 2 of 3
7 Sterilization process data of run 3 of 3
8 Process documentation sterilizer

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2 Introduction

2.1 Introduction of the test laboratory

SAL GmbH is accredited by the DAkkS (German accreditation body) as a test laboratory according to the directives 93/42/EEC, 90/385/EEC and DIN EN ISO/IEC 17025 for microbiological-hygienic and physical testing of cleaning, disinfection and sterilization processes. The accreditation is only valid for the scope specified by the annex to the accreditation certificate [D-PL-18398-02-02]. The German accreditation body is signatory to the multilateral agreements of the EA (European Co-operation for Accreditation), ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) for the mutual recognition of laboratory reports.

SAL GmbH is also recognized by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) as a laboratory according to Council Directives 93/42/EEC and 90/385/EEC and DIN EN ISO/IEC 17025 for microbiological-hygienic and physical testing of cleaning, disinfection and sterilization processes.

Copies of the certificates are enclosed (annex 1).

2.2 Job definition

According to Council Directive 93/42/EEC concerning medical devices, annex 1, clause 13.6 h) the manufacturer of reusable medical devices has to specify suitable reprocessing procedures. This requirement is detailed by standard EN ISO 17664 which requires in chapters 4.1 and 4.2 available objective evidence of a validated processing procedure for a medical device.

Tests are conducted to validate a sterilization process defined by the customer.

Tests for the validation of the sterilization processes are based on the standards:

- DIN EN ISO 17665-1:2006-11 "Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices"

The sterilization process is evaluated as valid, if the following requirements are fulfilled:

1. Verification of conditions for an overkill process ($F_0 \geq 15$ min) at those spots of the samples, that are most difficult to sterilize. (F_0 is a measure of microbiological lethality delivered by a moist heat sterilization process expressed in terms of the equivalent time, in minutes, at a temperature of 121,1 °C with reference to microorganisms with a z value of 10 K)
2. Proof of sterility (SAL $\leq 10^{-6}$ CFU/part) at those areas of the samples that are most difficult to sterilize
3. Proof of reproducibility of results in three sterilization cycles.

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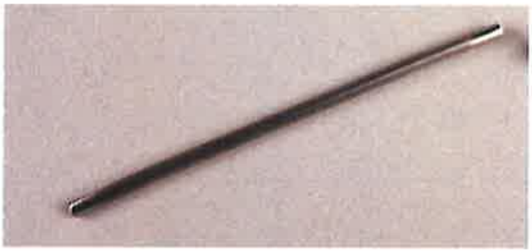
3 Material

3.1 Samples

Sample 1

Description	Electrode, straight
Manufacturer	DENLUX A/S – Dental Electronic A/S
Item number	K10030
Lot number	Not defined
Picture	

Sample 2

Description	Electrode, angled
Manufacturer	DENLUX A/S – Dental Electronic A/S
Item number	K10029
Lot number	Not defined
Picture	

Sample 3

Description	Rubber tip
Manufacturer	DENLUX A/S – Dental Electronic A/S
Item number	K10031
Lot number	Not defined
Picture	

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3.2 Packaging for sterilization

Pouches	Name	BOP DI
	Manufacturer	Amcor Flexibles SPS, France
	Item number	91BOP03260
	Batch number	137
	Description	Sterilization pouches
	Compliance	EN 868-1 and EN 868-5
	Material	Plastic foil and paper back

Samples are sealed once in sterilization pouches.

3.3 Sterilizer and sterilization process

Sterilizer	Name	Research sterilizer
	Serial number	1144
	Compliance	EN 867-4 and ISO 11140-4
	Manufacturer	Lautenschläger, Germany
Sterilization process	Air removal phase	3 evacuation steps 200 mbar to 1000 mbar pressure change rate 1000 mbar/min
	Sterilant injection	pressure change rate 1000 mbar/min
	Holding time	2:00 min at 134°C
	Drying phase	7:00 min at 100 mbar or less

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3.4 Additional Materials

Temperature measuring equipment	Name	Tracksense Pro
	Manufacturer	Ellab, Denmark
	Accuracy	± 0.1 K
	Calibration	Calibration certificates enclosed (annex 2)
Pressure measuring equipment	Name	Tracksense Pro
	Manufacturer	Ellab, Denmark
	Accuracy	± 15 mbar
	Calibration	Calibration certificate enclosed (annex 2)
Temperature reference	Name	Drago Basic
	Manufacturer	Isotech, UK
	Accuracy	± 0.05 K
	Calibration	Calibration certificate enclosed (annex 2)
Spore suspension	Name	gke Steri Record spore suspension
	Manufacturer	gke GmbH, Germany
	Item number.	228-108
	Species	*Geobacillus stearothermophilus*
	Lot number	308300328
	Nominal population	1.5 x 10^8 CFU/mL
	$D_{121°C}$-value	1.7 min
	Expiry date	07-2020 (mm-yyyy)
Reference Spore suspension	Name	Reference Spore suspension
	Manufacturer	SAL GmbH, In-house production
	Species	*Geobacillus stearothermophilus*
	Item number.	Not available
	Lot number	Not available
	Nominal population	500 CFU/ml
Culture medium	Name	B-S-V-CM
	Manufacturer	gke GmbH, Germany
	Item number.	223-100
	Lot number	597-2022
Incubator	Name	B6 Incubator
	Manufacturer	Heraeus GmbH, Germany
	Serial number.	95108324

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4 Methods

4.1 Determination of the locations most difficult to sterilize

The samples are analyzed for areas difficult to sterilize. Critical areas are selected as test spots as follows:

Areas difficult to sterilize	Selection of the test spot
Hollow devices, narrow lumina, splits, screws	centric in the area of the largest dimensions or as far as possible away from the opening of hollow devices
Porous areas, cotton materials	In the geometric center
Areas of high weight	area of the highest mass and, if applicable, the lowest heat conductivity
Areas with seals	on sealed areas (under O-rings, contact surface of seals)
Areas with materials, which could influence the resistance of germs	On each type of relevant material
Not dismountable areas	If possible, the area is dismounted for the test and evaluated according to areas which are difficult to sterilize as described before.

Selected test spots are detailed in chapter 5.

4.2 Sterilization tests

4.2.1 Contamination

- Selected test spots are inoculated with spore suspension and dried. Each test spot has a population of not less than 10^6 spores.
- Not inoculated samples are used as controls
- Inoculated samples and controls are packaged for sterilization as described in chapter 3.

4.2.2 Sterilization

- Three consecutive sterilization runs are performed with at least one inoculated test item of each design in each run (straight electrode, angled electrode, rubber tip).
- The test items and controls are placed in the center of the sterilizer chamber.
- Temperature loggers are fixed to the samples.
- A pressure logger is placed in the sterilizer chamber.
- The samples are sterilized in a partial cycle (sterilization time reduced to 2:00 min).

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4.2.3 *Evaluation of sterilization efficacy*

- Inoculated samples and controls are evaluated under sterile conditions as follows:
  - Inoculated samples and controls are transferred to flasks with culture medium.
  - 1 ml sterile water is added to one control (negative control, sterility control)
  - 0,1 ml reference spore suspension is added to one control (positive control, growth control)
  - All flasks and controls are incubated for 7 days at 57 °C.
  - All flasks are check for microbiological growth, indicated by turbidity of the culture media.

5 Results

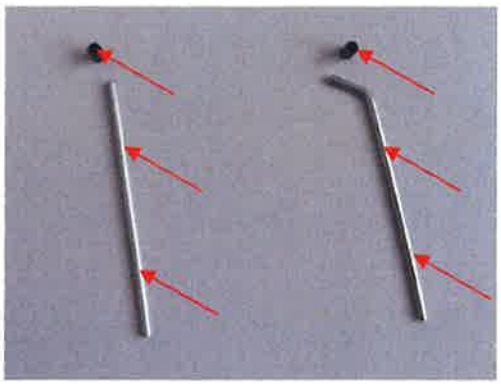
5.1 Test spots sterilization

The following test spots are selected for the sterilization process:

Areas difficult to sterilize	Selection of the test spot
Hollow devices, narrow lumina, splits, screws	Rubber tip
Areas with materials, which could influence the resistance of germs	Rubber tip, Electrodes

5.2 Photo documentation

Inoculated sample, arrows indicate inoculated areas (sterilization)



Packaged samples (sterilization)

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Samples places in sterilizer

5.3 Results sterilization tests

Criterion	Acceptance criteria	Run 1 of 3	Run 2 of 3	Run 3 of 3
Sterilization time	≥ Specified value as per partial cycle definition (reduced exposure time)	passed	passed	passed
Sterilization temperature (including sample temperature)	Specified temperature as per process definition -0 / + 3 °C	passed	passed	passed
Equilibration time	≤ 15 seconds	passed	passed	passed
F_0 value (including sample temperature)	≥ 15 min	passed	passed	passed
Inactivation of biological indicators in the partial cycle	Inactivation of all spores	passed	passed	passed
Negative control	No growth		passed	
Positive control	Growth		passed	

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6 Evaluation

A sterilization process is validated. The tested process and samples are specified by the customer. All material and methods are described in chapter 3 and 4 of this report.

The sterilization process is evaluated as valid, because the following requirements are fulfilled:

1. Verification of conditions for an overkill process ($F_0 \geq 15$ min) at those spots of the samples, that are most difficult to sterilize.
2. Proof of sterility (SAL $\leq 10^{-6}$ CFU/part) at those spots of the samples that are most difficult to sterilize
3. Proof of reproducibility of results in three sterilization cycles.

A partial sterilization cycle with half of the specified exposure time inactivates biological indicators with a population of at least 10^6 CFU on the tested sample according to DIN EN ISO 11138-3. Based on this fact, it is concluded that a sterilization cycle with full exposure time reduces the population of biological indicators by 12 $\log_{10}$ reduction steps to a survival probability of 10^{-6} CFU/sample or better (SAL $\leq 10^6$ CFU/product)

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The results are valid exclusively for the tested sample and are reproducible only under the exact conditions under which they were determined. For further information, do not hesitate to contact us.

Thank you very much for your order.

Waldems, 2020-03-27 (yyyy-mm-dd)

Place, date

Philipp Kloos

Validation technician

Waldems, 2020-03-27 (yyyy-mm-dd)

Place, date

Dr. Kerstin Kruse

head of process engineering laboratory

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