

Protocol No: TTS-0004901

## **CEYLAN MEDİKAL**

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## **ANNEXES**

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**TTS Laboratuvar Hizmetleri İth. İhr. San. ve Tic. Ltd. Şti.**

Çakmaklı Mah. Hadımköy Yolu Cad. Ufuk Plaza Sitesi No:57/20 Büyükçekmece 34500 İSTANBUL / TÜRKİYE

**Tel:** 0212 886 58 87 **Mobile:**0553 474 22 43

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# STEAM STERILIZATION VALIDATION

Protocol No: TTS-0004901

## ANNEX 1 STEAM STERILISATION PROCESS RISK ANALYSIS

**TTS Laboratuvar Hizmetleri İth. İhr. San. ve Tic. Ltd. Şti.**

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**STEAM STERILIZATION PROCESS VALIDATION**

NO	RISK ANALYSIS					RISK ASSESSMENT		RISK REDUCTION	RESIDUAL RISK ASSESSMENT			
	Hazard	Failure mode	Potential Impacts	Severity	Occurrence	RPN	Acceptability	Mitigation Measures	Severity	Occurrence	RPN	Acceptability
1	Leakage of Water Reservoir during Sterilization Process	Improper sealing, manufacturing defects, high-pressure steam	Compromised sterility, infection risk to neonate	5	4	20	IT	Implement stringent quality control measures during manufacturing Regular maintenance checks for lid integrity Provide clear sealing instructions to users	5	1	5	AFAP
2	Overheating of Water Reservoir	Temperature control malfunction, operator error	Endangered neonate safety, equipment functionality disruption	5	3	15	IT	Implement redundant temperature monitoring systems Provide operator training on sterilization process Install automatic shutoff mechanisms	5	1	5	AFAP
3	Equipment Failure during Sterilization	Electrical malfunction, mechanical failure	Compromised sterility, disruption of neonatal care	4	3	12	IT	Regular maintenance and calibration - Implement backup systems Have contingency plan for immediate response	4	1	4	AFAP
4	Chemical Residue in Water Reservoir	Inadequate rinsing, improper use of sterilization chemicals	Harmful exposure to neonate, compromised sterile environment	4	3	12	IT	Ensure thorough rinsing procedures after chemical sterilization Provide training on proper chemical usage and handling Regularly test water for chemical residues	4	1	4	AFAP
5	Incomplete Sterilization of Water Reservoir	Insufficient sterilization time, inadequate steam penetration	Risk of microbial contamination, compromised sterility	5	2	10	AFAP	Validate sterilization cycles for adequate time and steam penetration - Implement monitoring systems for sterilization effectiveness - Conduct regular audits of sterilization processes	5	1	5	AFAP
6	Water Reservoir Material Degradation	Material aging, exposure to harsh chemicals or temperatures	Risk of particulate contamination, compromised functionality	4	3	12	IT	Use high-quality materials resistant to degradation Implement regular inspection and replacement schedules Avoid exposure to harsh chemicals or extreme temperatures	4	1	4	AFAP
7	Steam Pressure Fluctuations during Sterilization	Steam generator issues, improper maintenance	Risk of equipment damage, compromised sterilization	4	3	12	IT	Conduct regular maintenance and calibration of steam generators Monitor steam pressure during sterilization cycles Implement safety mechanisms to mitigate pressure fluctuations	4	1	4	AFAP
8	Incorrect Loading of Water Reservoir into Sterilization Equipment	Human error, lack of training	Improper sterilization, risk of equipment damage	3	4	12	IT	Provide comprehensive training on proper loading procedures Implement visual aids or checklists for loading instructions Conduct regular competency assessments for operators	3	1	3	AFAP
9	Power Outage during Sterilization Process	Electrical grid failure, equipment malfunction	Compromised sterility, risk of incomplete sterilization	4	2	8	AFAP	Install backup power systems or uninterruptible power supplies Implement protocols for resuming sterilization after power outage Conduct regular testing of backup power systems	4	2	8	AFAP
10	Steam Quality Issues	Water impurities, inadequate steam generation or filtration	Risk of microbial contamination, compromised sterilization	4	3	12	IT	Implement water purification systems to ensure steam quality - Regularly test and monitor steam quality parameters - Conduct maintenance and replacement of steam generation and filtration systems	4	2	8	AFAP

**STEAM STERILIZATION PROCESS VALIDATION**

NO	RISK ANALYSIS					RISK ASSESSMENT		RISK REDUCTION	RESIDUAL RISK ASSESSMENT			
	Hazard	Failure mode	Potential Impacts	Severity	Occurrence	RPN	Acceptability	Mitigation Measures	Severity	Occurrence	RPN	Acceptability
11	Corrosion of Water Reservoir	Corrosive chemicals, improper maintenance	Risk of metal contamination, compromised functionality	4	3	12	IT	Use corrosion-resistant materials for construction Implement regular inspection and maintenance of reservoir Monitor chemical levels and pH balance of water	4	1	4	AFAP
12	Air Trapped in Water Reservoir during Sterilization	Improper loading, inadequate venting	Risk of microbial growth, compromised sterilization	4	4	16	IT	Implement proper loading procedures to prevent air entrapment Ensure adequate venting during sterilization Conduct validation tests to verify sterilization effectiveness	4	1	4	AFAP
13	Sterilization Process Interruption	Equipment malfunction, human error	Risk of incomplete sterilization, compromised sterility	4	3	12	IT	Implement monitoring systems to detect process interruptions - Provide operator training on handling interruptions - Develop contingency plans for resuming interrupted sterilization processes	4	1	4	AFAP
14	Contamination from External Sources	Poor handling practices, environmental contaminants	Risk of microbial contamination, compromised sterility	4	2	8	AFAP	Implement strict protocols for handling and storage Conduct regular environmental monitoring Provide staff training on infection control measures	4	2	8	AFAP
15	Inadequate Drainage System	Design flaws, blockages	Risk of water accumulation, equipment damage	4	3	12	IT	Design and implement effective drainage systems Regularly inspect and clear drainage pathways Conduct testing to ensure proper drainage functionality	4	1	4	AFAP



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# STEAM STERILIZATION VALIDATION

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## ANNEX 2 EQUIPMENT DOCUMENTATION

**TTS Laboratuvar Hizmetleri İth. İhr. San. ve Tic. Ltd. Şti.**

Çakmaklı Mah. Hadımköy Yolu Cad. Ufuk Plaza Sitesi No:57/20 Büyükçekmece 34500 İSTANBUL / TÜRKİYE

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## ANNEX 2 EQUIPMENT DOCUMENTATION 2.1. Cycle Outputs

**TTS Laboratuvar Hizmetleri İth. İhr. San. ve Tic. Ltd. Şti.**

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NÜVE STEAMART OT 300

SERİ NO 20417

FİRMA: TTS Laboratuvar Hiz.

ADRES: B.çekmece / İstanbul

TEL: 0212 886 5 887

SAAT : 09:00:00

TARİH : 2024-10-02

Program: Katı Program

Ön Isıtma : 50.0°C

Safha	Sıcaklık °C	Zaman Dak.
Başlama	25.9	0:00:00
Isıtma	90.0	0:04:04
Isıtma	90.1	0:04:36
Isıtma	85.3	0:08:36
Isıtma	15.1	0:08:36
Stril. Başlama	134.1	0:12:36
Stril. Sonu	134.3	0:15:36
Soğutma	134.9	0:19:32
Soğutma	110.2	0:20:15
Soğutma	90.1	0:27:44
Soğutma	88.3	0:28:25
Soğutma	76.9	0:35:14
İşlem Sonu	74.5	0:35:45

İŞLEM TAMAMLANDI

Stril. Süresi : 3

Bitiş Zamanı : 09:36:02

2024 1 3903

İmza:

NÜVE STEAMART OT 300

SERİ NO 20417

FİRMA: TTS Laboratuvar Hiz.

ADRES: B.çekmece / İstanbul

TEL: 0212 886 5 887

SAAT : 09:38:02

TARİH : 2024-10-02

Program: Katı Program

Ön Isıtma : 50.0°C

Safha	Sıcaklık °C	Zaman Dak.
Başlama	51.8	0:00:00
Isıtma	79.9	0:04:04
Isıtma	95.1	0:04:36
Isıtma	84.2	0:08:36
Isıtma	101.3	0:08:36
Stril. Başlama	134.2	0:12:36
Stril. Sonu	134.2	0:15:36
Soğutma	135.2	0:19:32
Soğutma	109.9	0:20:15
Soğutma	92.1	0:27:44
Soğutma	89.1	0:28:25
Soğutma	76.9	0:35:14
İşlem Sonu	74.4	0:35:45

İŞLEM TAMAMLANDI

Stril. Süresi : 3

Bitiş Zamanı : 10:14:07

2024 1 3904

İmza:

NÜVE STEAMART OT 300

SERİ NO 20417

FİRMA: TTS Laboratuvar Hiz.

ADRES: B.çekmece / İstanbul

TEL: 0212 886 5 887

SAAT : 10:16:07

TARİH : 2024-10-02

Program: Katı Program

Ön Isıtma : 50.0°C

Safha	Sıcaklık °C	Zaman Dak.
Başlama	51.8	0:00:00
Isıtma	79.9	0:04:04
Isıtma	95.1	0:04:36
Isıtma	84.2	0:08:36
Isıtma	101.3	0:08:36
Stril. Başlama	134.2	0:12:36
Stril. Sonu	134	0:15:36
Soğutma	135.2	0:19:32
Soğutma	109.9	0:20:15
Soğutma	92.1	0:27:44
Soğutma	89.1	0:28:25
Soğutma	76.9	0:35:14
İşlem Sonu	74.2	0:35:45

İŞLEM TAMAMLANDI

Stril. Süresi : 3




Bitiş Zamanı : 10:52:10

2024 1 3905

İmza:

Protocol No: TTS-0004901

ANNEX - 2  
EQUIPMENT DOCUMENTATION  
ANNEX-2.2 Autoclave Calibration Certificate

	<b>DK DONANIM KALİBRASYON</b> Yeniköy Mh. Hasbek Sk. Nasrullahzade Sit. A Blok No: 49/A Melikgazi / KAYSERİ	 AB-0179-K S302234 02.2022	
<b>KALİBRASYON SERTİFİKASI</b> Calibration Certificate			
Cihazın Sahibi/Adresi Customer / Address	:	TTS LABORATUVAR HİZMETLERİ İTHALAT İHRACAT SAN VE TİC LİMİTED ŞİRKETİ ÇAKMAKLI MAH. HADIMKÖY YOLU CAD. UFUK PLAZA NO: 57 İÇ KAPI NO: 20 BÜYÜKÇEKMECE/ İSTANBUL	
İstek Numarası Order No	:	DK7272	
Makine / Cihaz Instrument/Device	:	OTOKLAV	
İmalatçı Manufacturer	:	NÜVE	
Tip Type	:	OT 300	
Seri Numarası Serial Number	:	02.0417	
Kalibrasyon Tarihi Date of Calibration	:	24.02.2022	
Sertifikanın Sayfa Sayısı Number of Pages of the Certificate	:	3	
<p>Bu kalibrasyon sertifikası, Uluslararası Birimler Sisteminde (SI) tanımlanmış birimleri realize eden ulusal ölçüm standartlarına izlenebilirliği belgeler. This calibration certificate documents the traceability to national standards, which realize the unit of measurement according to the International System of Units (SI).</p> <p>Kalibrasyon laboratuvarı olarak faaliyet gösteren Donanım Kalibrasyon, TÜRKAK'tan AB-0179-K dosya numarası ile TS EN/ISO 17025:2017 standardına göre akredite edilmiştir. Donanım Kalibrasyon accredited by TÜRKAK under registration number AB-0179-K for TS EN/ISO 17025:2017 as Calibration Laboratory"</p> <p>Türk Akreditasyon Kurumu(TÜRKAK) kalibrasyon sertifikalarının tanınırılığı konusunda Avrupa Akreditasyon Birliği(EA) ile Çok Taraflı Anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği(ILAC) ile karşılıklı tanıma anlaşması imzalamıştır. Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the recognition of calibration certificates</p> <p>Ölçüm sonuçları, genişletilmiş ölçüm belirsizlikleri ve kalibrasyon metotları bu sertifikanın tamamlayıcı kısmı olan takip eden sayfalarda verilmiştir. The measurement s, the uncertainties with confidence probability and calibration methods are given on the following pages which are part of this certificate.</p>			
Mühür/Kaşe Seal	Yayımlandığı Tarih Date	Kalibrasyonu Yapan Calibrated by	Onaylayan Approval
	18.03.2022	HALİL İBRAHİM POLAT	ALPASLAN KÜÇÜKKARASU
		e-imzalıdır.	e-imzalıdır.

Bu sertifika, laboratuvarın yazılı izni olmadan kısmen kopyalanıp çoğaltılamaz. İmzasız sertifikalar geçersizdir.  
This certificate shall not be reproduced other than in full except with the permission of the laboratory. Calibration certificates without signature are not valid.

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# STEAM STERILIZATION VALIDATION

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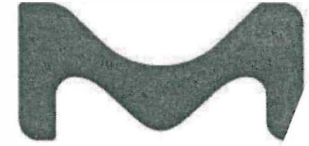
**ANNEX 3**  
**BIOLOGICAL INDICATOR INFORMATION**  
**ANNEX-3.1 Biological Indicator Certificate**

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# Certificate of Analysis

1.10274.0002 Sterikon® plus Bioindicator for checks on autoclaving  
Batch Z0827474

	Spec. Values	Batch Values
Appearance	opalescent and reddish violet	passes test
Number of viable spores per ampule	$5.0 \cdot 10^5 - 1.0 \cdot 10^7$	$1.0 \cdot 10^6$
Growth (35 °C)	no growth	passes test
Growth (60 °C)	growth	passes test
Performance test (6 min, 121 °C)	Survival time 6 min/121 °C	passes test
Performance test (15 min, 121 °C)	Kill time 15 min/121 °C	passes test
D value (121 °C)	1.5 - 2.0 min	1.7 min
Z value	7.0 - 10.0 °C	9.8 °C
Identity	Geobacillus stearo-thermophilus ATCC 7953	passes test

The determination of the D-value is based on the Stumbo-Murphy-Cochran method.

The identity control is carried out via MicroSeq-System.

Organism: Geobacillus stearothermophilus ATCC 7953 (sporulation optimized).  
Ampoules: 2 ml.  
Storage temperature: +2° to +8°C.

Date of release (DD.MM.YYYY) 24.05.2023  
Expiry date (DD.MM.YYYY) 19.10.2024

Dr. Lukas Mechler  
Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.



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# STEAM STERILIZATION VALIDATION

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## ANNEX 4 TEST REPORT

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AB-1802-T

TTS-0004901

10-24

TEST REPORT

Report No/ Rev.No/ Report Date : TTS-0004901 / 0 / 18.10.2024  
Sample Name/ Description : CM-006252 Ferris-Smith-Kerrison- Cutting 40° Forward 1 mm Interchangeable Tipped Spinal Disc Rongeur  
Product/License Holder : CEYLAN MEDİKAL İmalat İthalat İhracat Dış Tic. (Fatma CEYLAN)  
Production Location Address : Yenicami OSB Mah. 5. Cadde No: 6/4 KAVAK/SAMSUN/TÜRKİYE  
2024-001  
Lot No/Charge-Serial No : 2024-002  
2024-003  
Formulation Content : -  
Formulation Form : Solid  
Sample Packaging : Non-Sterile  
Sample Acceptance Date : 01.03.2024  
Place of Sample Arrival : Yenicami OSB Mah. 5. Cadde No: 6/4 KAVAK/SAMSUN/TÜRKİYE  
Reason for Sample Arrival and Seal Status : Special Request / Unsealed  
Number/Quantity of Samples : 9 Pcs.  
Production - Expiration Date : 07.2023 / NA  
Explanations : The test was performed within the scope of Validation.  
Analysis Method : ISO 11737-1, ISO 11737-2, ISO 11138-1, ISO 11138-3, TS 5172 EN ISO 13402 and ASTM-F 1089 Standards and Ph. Eur. Method 2.6.1 Guidelines were applied.  
Test Start-End Date : 16.09.2024-18.10.2024

TTS Laboratuvar Hizmetleri İthalat İhracat San. ve Tic. Ltd. Şti. has been accredited by TÜRKAK according to TS EN ISO/IEC 17025:2017 Standard with Accreditation File Number AB-1802-T. The Turkish Accreditation Agency (TÜRKAK) has signed a Multilateral Agreement with the European Accreditation Association (EA) and a mutual recognition agreement with the International Laboratory Accreditation Cooperation (ILAC) for the recognition of test reports. If declared, the expanded measurement uncertainty is the standard uncertainty multiplied by the expansion coefficient, taken as k=2, and provides 95% reliability.

1. No part of this analysis report may be used alone or separately.
2. This report cannot be used in judicial-administrative proceedings and for advertising purposes..
3. Test results are valid for the specimens tested and described in this test report.
4. Sampling is not performed by TTS. Measurement uncertainty due to sampling is not taken into account. Problems that may arise due to sampling are the responsibility of the Customer.
5. This report may not be reproduced without the consent of the laboratory.
6. Unsigned and unstamped reports are invalid.
7. The units of limit values are the same as the units of findings.
8. \* marked analyzes are covered by accreditation.
9. Abbreviations; E: Evaluation. A: Appropriate. N.E.: Not Eligible. U.E.: Unable to Evaluate. R.: Recovery. M.U.: Measurement Uncertainty. M.L: Measurement Limit.

Analyzer  
Yeşim RUMELİ  
Microbiology Analysis Laboratory Unit Staff



Approved by  
Damla DAMAR BAŞSU  
Laboratory Manager

Date

18.10.2024

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TEST REPORT

AB-1802-T  
TTS-0004901  
10-24

Analysis	Limit	Result			Method	Evaluation
		2024-001	2024-002	2024-003		
Sterility Test Fungi and Aerobic Bacteria	No Reproduction	No Growth	No Growth	No Growth	ISO 11731-2 EP. 2.6.1	E
Sterility Test Anaerobic and Aerobic Bacteria	No Reproduction	No Growth	No Growth	No Growth		E
Negative Control	No Reproduction	No Growth				E
Positive Control	Must Reproduce	Growth Observed				E

Biological Indicator No	1.Cycle	2. Cycle	3. Cycle	Acceptance Criteria
BI 1	No Growth	No Growth	No Growth	No Reproduction
BI 2	No Growth	No Growth	No Growth	
BI 3	No Growth	No Growth	No Growth	
Negative Control	No Growth	No Growth	No Growth	
Positive Control	Growth Observed	Growth Observed	Growth Observed	Must Reproduce

Cycles were carried out on 02.10.2024 at 134°C for 3 min.

Analyze	Lot No	Acceptance Criteria	Result			
			After Autoclave	After Boiling Water Treatment	After Copper Sulfate Treatment	After Heat Treatment
CORROSION DETECTION TEST	2024-001	No Corrosion Should Be Seen	No Corrosion Seen	No Corrosion Seen	No Corrosion Seen	No Corrosion Seen
	2024-002		No Corrosion Seen	No Corrosion Seen	No Corrosion Seen	No Corrosion Seen
	2024-003		No Corrosion Seen	No Corrosion Seen	No Corrosion Seen	No Corrosion Seen

Analyzer  
Yeşim RUMELİLİ  
Microbiology Analysis Laboratory Unit Staff



Date  
18.10.2024

Approved by  
Damla DAMAR BAŞSU  
Laboratory Manager

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