TS EN 868-8 STANDARD
ANNEX-F/G TESTS
VALIDATION REPORT

Protocol Number	:	V270521-01
Report Number	:	AYA-VR080621-01
Date	:	08.06.2021
Revision Number	:	02
Revision Date	:	**23.01.2024**

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Report No: AYA-VR080621-01 Rev.02 **08 June 2021**

1. CONTENTS

2. TABLE INDEX

Report No: AYA-VR080621-01 Rev.02 **08 June 2021**

3. REPORT APPROVAL PAGE

With this Report, it has been observed that the Performance Adequacy of CUSTOMER products in accordance with the TS EN 868-8 Standard Annex-F / Annex-G tests were evaluated, revised and fulfilled the requirements of the relevant standard.

AYA			
Approved By	**Title**	**Signature**	**Date**
Merve YAZ	Sterilization & Validation Manager		23.01.2024
Asena Hatiren YÜZAK	Quality System Manager		23.01.2024
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CUSTOMER			
Approved By	**Title**	**Signature**	**Date**
Ahmet AYDEMİR	General Manager		23.01.2024
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4. SCOPE

This Validation Report has been prepared on the basis of the Validation Protocol numbered V270521-01 published on 27.05.2021 and the TS EN 868-8 Standard Annex-F / Annex-G tests.

4.1. Products Covered by Validation

The CUSTOMER has requested the validation studies to be carried out on the product given in Table 4.1. (Validation Report ANNEX-1).

Table 4.1 Product Groups

Product Name	Lot No
Biobarrier Full Size Sterilization Container *(Sample Size: 580x280x260 mm)*	2102492
Full Size Container Bottom Non-Perforated (Sample Size: 580x280x260 mm)	2102498

4.2. Steam Sterilization Unit and Biological Indicator Information

In the TS EN 868-8 Standard Annex-F / Annex-G tests, the Performance Validation Studies have been carried out before and the AYA Steam Sterilization Unit documented in the Report No. AYA2020-302-001 was used.

Table 4.2 Steam Sterilization Unit Information

Brand	NÜVE
Model	OT 300
Serial Number	03.0034
Volume	300 L

Table 4.3 Biological Indicator Information

Test Microorganism	*Geobacillus stearothermophilus*
Biological Indicator Type	SCBI
Lot Number	DDN112022
D Value for Steam (134 °C)	1,5 min.
Bacteria Population	1.0×10^6

Biological Indicator Information and Test Reports are given in the Validation Report ANNEX-2.

5. VALIDATION STUDY AND ITS RESULTS

5.1. Annex-F Determination of Sterilization Performance

Validation Cycle	Number of Studies	Tests to Be Performed	Acceptance Criteria
Annex-F Determination of Sterilization Performance	3	Biological Indicator Sterility Test	No growth in biological indicators
		Datalogger Temperature-Pressure Distribution Test	Temperature difference between datalogger should not exceed 2 °C.

Table 5.1 Biological Indicator Sterility Test Results - Biobarrier Full Size Sterilization Container

Product Name	Biobarrier Full Size Sterilization Container			
Biological Indicator No	**1st cycle**	**2nd cycle**	**3rd cycle**	**Acceptance Criteria**
BI 1 (in container)	No Growth	No Growth	No Growth	**No Growth**
BI 2 (conteiner top)	No Growth	No Growth	No Growth	
BI 3 (in autoclave)	No Growth	No Growth	No Growth	
Negative Control	No Growth	No Growth	No Growth	
Pozitive Control	Growth	Growth	Growth	**Growth Observed**

Table 5.2 Biological Indicator Sterility Test Results - *Full Size Container Bottom Non-Perforated*

Product Name	*Full Size Container Bottom Non-Perforated*			
Biological Indicator No	**1st cycle**	**2nd cycle**	**3rd cycle**	**Acceptance Criteria**
BI 1 (in container)	No Growth	No Growth	No Growth	**No Growth**
BI 2 (conteiner top)	No Growth	No Growth	No Growth	
BI 3 (in autoclave)	No Growth	No Growth	No Growth	
Negative Control	No Growth	No Growth	No Growth	
Pozitive Control	Growth	Growth	Growth	**Growth Observed**

Biological Indicator Test Results Validation Report can be seen in ANNEX-3.1.

Report No: AYA-VR080621-01 Rev.02 **08 June 2021**

Table 5.3 Datalogger Temperature-Pressure Distribution Results - Biobarrier Full Size Sterilization Container

Product Name	**Biobarrier Full Size Sterilization Container**		
Cycle No	**1st cycle**	**2nd cycle**	**3rd cycle**
Autoclave Working Temperature and Time	134°C / 5 min.	134°C / 5 min.	134°C / 5 min.
Test Date	04.06.2021	04.06.2021	04.06.2021
Start Time	14:10:00	15:05:00	15:44:00
Exposure Start Time	14:26:30	15:17:00	15:57:30
Exposure Finish Time	14:31:30	15:22:00	16:02:30
Finish time	14:54:30	14:54:30	16:27:00
Exposure Time	00:05:00	00:05:00	00:05:00
Vacuum Drying Pressure (Bar)	-0.693	-0.695	-0.692
Vacuum Drying Temperature (°C)	95.4	94.5	95.5
Vacuum Drying Time	15 min.	15 min.	15 min.
Max. Temperature (After Stabilization)	136,48	136,69	136,37
Min. Temperature (After Stabilization)	134,56	134,83	135,18
Deviation Between Datalogger After Stabilization Period	1,92	1,86	1,19
Compliance with Acceptance Criteria	Suitable ☒ Not Suitable ☐	Suitable ☒ Not Suitable ☐	Suitable ☒ Not Suitable ☐

Report No: AYA-VR080621-01 Rev.02 **08 June 2021**

Table 5.4 Datalogger Temperature-Pressure Distribution Results - *Full Size Container Bottom Non-Perforated*

Product Name	***Full Size Container Bottom Non-Perforated***		
Cycle No	**1st cycle**	**2nd cycle**	**3rd cycle**
Autoclave Working Temperature and Time	121°C / 15 min.	121°C / 15 min.	121°C / 15 min.
Test Date	26.05.2021	26.05.2021	26.05.2021
Start Time	16:00:00	17:25:00	18:55:00
Exposure Start Time	16:10:30	17:38:30	19:07:00
Exposure Finish Time	16:25:30	17:53:30	19:22:00
Finish time	16:50:00	18:15:00	19:45:00
Exposure Time	00:15:00	00:15:00	00:15:00
Vacuum Drying Pressure (Bar)	-0.698	-0.700	-0.701
Vacuum Drying Temperature (°C)	89.5	88.7	89.4
Vacuum Drying Time	15 min.	15 min.	15 min.
Max. Temperature (After Stabilization)	123,63	123,85	123,56
Min. Temperature (After Stabilization)	121,7	121,9	122,35
Deviation Between Datalogger After Stabilization Period	1,93	1,95	1,21
Compliance with Acceptance Criteria	Suitable ☒ Not Suitable ☐	Suitable ☒ Not Suitable ☐	Suitable ☒ Not Suitable ☐

Datalogger Temperature-Pressure Distribution Results Validation Report can be seen in ANNEX-3.2.

ANNEX-3: Annex-F Determination of Sterilization Performance

3.1. Biological Indicator Test Results
3.2. Datalogger Temperature-Pressure Distribution Results
3.3. Biological Indicator and Datalogger Layout
3.4. Device Outputs

5.2. Annex-G Dryness Determination Test

Validation Cycle	Number of Studies	Tests to Be Performed	Acceptance Criteria
Annex-G Dryness Determination Test	3	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$ m_1, is the mass of the Empty Container,in grams m_2, is the mass of the loaded Container before the cycle, in grams m_3, is the mass of the loaded Container at completion of the cycle, in grams.	The calculated value should not exceed 1%.

Table 5.5 Dryness Determination Test Results - Biobarrier Full Size Sterilization Container

Product Name		Biobarrier Full Size Sterilization Container			
Sterilization No	m_1	m_2	m_3	Calculation	Result
1.Sterilization	4.881,17 g	5.181,09 g	5.178,2 g	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$	%0,9636
2.Sterilization	4.878,91 g	5.180,86 g	5.178,15 g	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$	%0,8975
3.Sterilization	4.877,58 g	5.179,87 g	5.177,56 g	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$	%0,7642

Table 5.6 Dryness Determination Test Results - *Full Size Container Bottom Non-Perforated*

Product Name		Full Size Sterilization Container			
Sterilization No	m_1	m_2	m_3	Calculation	Result
1.Sterilization	4.514,39 g	4.815,14 g	4.812,29 g	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$	%0,9476
2.Sterilization	4.513,04 g	4.815,17 g	4.812,55 g	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$	%0,8672
3.Sterilization	4.512,87 g	4.814,14 g	4.811,7 g	$\frac{m_3 - m_2}{m_2 - m_1} \times 100\,\%$	%0,8099

Report No: AYA-VR080621-01 Rev.02 **08 June 2021**

6. RESULT

When the Validation Study Results were evaluated, it was observed that TS EN 868-8 Standard Annex-F / Annex-G Tests were met with all parameters.

7. REFERENCES

TS EN 868-8	:	Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
TS EN 285	:	Sterilization - Steam Sterilizers - Large sterilizers
TS EN ISO 13485	:	Medical Devices-Quality Management Systems-Conditions for Legislative Purposes
TS EN ISO 11138-1	:	Sterilization of health care products-Biological Indicators-Part 1: General requirements
TS EN ISO 11138-3	:	Sterilization of Health Care Products - Biological Indicators - Part 3: Biological Indicators for Moist Heat Sterilization Processes
AYA.TL.3.43	:	BI Sterility Control Instruction

8. DEVIATIONS

Has there been a deviation? YES ☐ NO ☒

Deviation No	Deviation Remedied?	Explanation

9. REVISION HISTORY

Revision No	Page Information	Revision Explained	Revision Date
01	5,7,8,11	1.) Added sample size, 2.) Vacuum drying pressure,temperature and time added. 3.) Device outputs added to attachments	31.08.2023
02	3,5,6,8,9	With the Customer Declaration, the product name Full Size Sterilisation Container 580x280x260 was revised as Full Size Container Bottom Non-Perforated 580x280x260.	23.01.2024

10. ANNEXES

ANNEX-1 VALIDATION REQUEST FORM

ANNEX-2 BIOLOGICAL INDICATOR INFORMATION AND TEST REPORTS

ANNEX-3 ANNEX-F DETERMINATION OF STERILIZATION PERFORMANCE

ANNEX-3.1 Biological Indicator Test Results

ANNEX-3.2 Datalogger Temperature-Pressure Distribution Results

ANNEX-3.3 Biological Indicator and Datalogger Layout

ANNEX-3.4 Device Outputs