

Information générale / General information

Lot de stérilisation # <i>Sterilization batch number #</i>	2540-2
Cycle # <i>Cycle #</i>	04-2 daté / <i>dated</i> 22.02.2010
Nom du client / bulletin de livraison <i>Customer name / delivery note</i>	Applimed SA / 13.05.2025
Date de réception <i>Date of reception</i>	13.05.2025
Nom du produit <i>Name of product</i>	Pallets Nr. 28015, 28016, 28017, 28018, 28019, 28020 (Detail see page 2)
Site de stérilisation <i>Sterilization site</i>	C.S.S.R. Groupe Applimed SA, CH – Châtel-St-Denis
Remarques / <i>Remarks</i> : N/a	

Données Processus Physiques / Physical Process Data

Temps préconditionnement <i>Preconditioning time</i>	≥ 12 h
Chambre de stérilisation <i>Sterilization chamber</i>	ST2
Date de stérilisation <i>Date of sterilization</i>	14.05.2025
Temps de dégazage <i>Degazing time</i>	≥ 12 h
Remarques / <i>Remarks</i> : N/a	

Données Processus Microbiologiques / Microbiological Process Data

Nbr d'indicateurs biologiques : <i>Nr. of biological indicators:</i>	min. 18 par charge total (15 m ³) <i>min. per total load (15 m³)</i>
Type d'indicateurs biologiques : <i>Type of biological indicators:</i>	Indicateur Biologique Autonome, <i>Bacillus atrophaeus</i> 10 ⁶ , ATCC No. 9372, selon ISO 11138-1 et -2 <i>Self contained Biological Indicator, Bacillus atrophaeus 10⁶, ATCC No. 9372, according to ISO 11138-1 and -2</i>
Date d'incubation <i>Date of incubation</i>	14.05.2025
Conditions d'incubation <i>Incubation conditions</i>	2 jours à 37°C ± 2°C <i>days at 37°C ± 2°C</i>
Nbr. avec croissance confirmée de <i>Bacillus atrophaeus</i> <i>Nr. with confirmed growth of Bacillus atrophaeus</i>	0 (zéro) récupérations pour les IB <i>(zero) recoveries for the BI's</i>
Remarques / <i>Remarks</i> : N/a	

Résultats des Contrôles Physiques et Microbiologiques / Results of Physical and Microbiological Controls

Les critères d'acceptation physiques et microbiologiques sont conformes aux spécifications établies lors de la Validation et requises dans la Carte client.
The physical and microbiological acceptance criteria are in compliance with the specifications established during the Validation and required in the Customer card.

C.S.S.R. Groupe Applimed SA - Approbation / Approval

Titre / <i>Title</i>	Date / <i>Date</i>	Signature / <i>Signature</i>
Production Responsable	16.05.2025	
Quality Control Responsable	16.05.2025	

Lot de stérilisation # <i>Sterilization batch number #</i>	2540-2
Date de stérilisation <i>Date of sterilization</i>	14.05.2025

Pallet Nr.	Art. Nr.	Lot Nr.
28015	1102254	25.05.07
28015	8001931 (IN150103)	25.05.13
28016	1102254	25.05.07
28016	8001719	25.05.13
28016	8001745	25.05.13
28017	1102254	25.05.07
28017	1101250 (1030420)	25.05.08
28018	1101250 (1030420)	25.05.08
28019	1101250 (1030420)	25.05.08
28020	1102254	25.05.07
28020	4901036	25.05.12

Sterilization number:

2540-2

Date of sterilization :

14.05.2025

Specification of cycle nr.: 04-2/ Revision: 0/ Date: 22.02.10

Evaluation

Parameter	Specification / Tolerance / Range	Actual data	Pass	Fail
Temperature in the pallet before loading into preconditioning	$\geq 16^{\circ}\text{C}$	24.1 $^{\circ}\text{C}$	Pass	-
1. Preconditioning				
1.1 Time in the cell (after closing doors)	Depending on the heating time of the cell	13 h 07	For information	
1.2 Time in the cell within RH % & T $^{\circ}\text{C}$ tolerances (set points reached + 30 min. stabilization)	12h - 24h	12 h 03	Pass	-
1.3 Temperature in the cell after stabilization	Min 45 $^{\circ}\text{C}$	49.6 $^{\circ}\text{C}$	Pass	-
	Max 55 $^{\circ}\text{C}$	50.9 $^{\circ}\text{C}$	Pass	-
1.4 Relative humidity in the cell after stabilization	Min 40% RH	53.5 % RH	Pass	-
	Max 70% RH	58.8 % RH	Pass	-
1.5 Transfer time from preconditioning to the chamber	Max 30 min.	8 min.	Pass	-
2. Sterilisation				
2.1 Initial vacuum	50 mbar $\pm$ 10 mbar	50 mbar	Pass	-
2.2 Rate of attainment of initial vacuum	15 min. – 60 min.	29 min.	Pass	-
2.3 Maximum allowed leak rate during a 10 minutes leak test	≤ 20 mbar	2 mbar	Pass	-
2.4 Relative humidity in the chamber during conditioning	Min 40% RH	54.8 % RH	Pass	-
	Max 70% RH	57.3 % RH	Pass	-
2.5 Conditioning time after the steam injection	30 min. $\pm$ 5 min.	30 min.	Pass	-
2.6 Chamber temperature during conditioning	Min 45 $^{\circ}\text{C}$	46.6 $^{\circ}\text{C}$	Pass	-
	Max 55 $^{\circ}\text{C}$	47.3 $^{\circ}\text{C}$	Pass	-
2.7 Δ P of first EO/CO ₂ injection	230 mbar $\pm$ 10 mbar	230 mbar	Pass	-
2.8 Time of first EO/CO ₂ injection	Max 25 minutes	10 min.	For information	
2.9 Δ P of second EO/CO ₂ injection	230 mbar $\pm$ 10 mbar	230 mbar	Pass	-
2.10 Time of second EO/CO ₂ injection	Max 25 minutes	10 min.	For information	
2.11 Pressure at the beginning of exposure time	Max. 880 mbar	811 mbar	Pass	-
2.12 Number of kg of EO/CO ₂ used	≥ 17 kg.	25.6 kg.	Pass	-
2.13 Theoretical calculated gas concentration (empty chamber)	≥ 680 mg EO / l	1024 mg ETO / l	Pass	-
2.14 Gas temperature at the admission to the chamber	$\geq 25^{\circ}\text{C}$	Min. 38.1 $^{\circ}\text{C}$	Pass	-
2.15 Chamber temperature during exposure time	Min 45 $^{\circ}\text{C}$	48.6 $^{\circ}\text{C}$	Pass	-
	Max 55 $^{\circ}\text{C}$	49.4 $^{\circ}\text{C}$	Pass	-
2.16 Relative humidity in the chamber during exposure time	Min 40% RH	49.3 % RH	Pass	-
	Max 70% RH	61.0 % RH	Pass	-
2.17 EO/CO ₂ exposure time	4 h – 0/+ 5 minutes	04 h 00	Pass	-
2.18 Airflow during injection & exposure time	No airflow alarm	No	Pass	-
2.19 Number of EO make-up	make-up performed if Δ P > 20 mbar	2 make-up(s)	For information	
2.20 Δ P for both first and second Nitrogen injections N ₂	Minimum 240 mbar	290 mbar	Pass	-
2.21 Pressure at EO/CO ₂ evacuation	80 mbar $\pm$ 10 mbar absolute	80 mbar	Pass	-
2.22 Evacuation time of EO/CO ₂	Max 60 minutes	23 min.	Pass	-
2.23 Pressure at rinsing steps	Min 60 mbar $\pm$ 10 mbar absolute	60 mbar	Pass	-
	Max 850 mbar $\pm$ 10 mbar absolute	850 mbar	Pass	-
2.24 Air inlet time per rinsing step	Min 5 minutes	12 min.	Pass	-
	Max 20 minutes	12 min.	Pass	-
2.25 Evacuation time at rinsing steps	Min 15 minutes	22 min.	Pass	-
	Max 60 minutes	24 min.	Pass	-
2.26 Number of air rinsing steps	5 evacuations / air-inlet-steps	5 rinsing steps	Pass	-
3. Degassing				
3.1 Aeration time in the aeration cell (after closing doors)	Depending on the heating time of the cell	12 h 55	For information	
3.2 Aeration time within T $^{\circ}\text{C}$ tolerances (set point reached)	minimum 12h	12 h 30	Pass	-
3.3 Aeration temperature in the aeration cell after stabilization	Min 45 $^{\circ}\text{C}$	49.6 $^{\circ}\text{C}$	Pass	-
	Max 55 $^{\circ}\text{C}$	51.1 $^{\circ}\text{C}$	Pass	-
3.4 Air mixing rate	Min 20 vol/h.	79 vol/h	Pass	-

Result of the cycle check and approval:

The performance of the sterilization cycle nr.: 04-2/22.02.10

☒ was in compliance = the cycle is approved.☐ was not in compliance = procedure according to SOP 8.3 and 8.5.2, production report nr.:

n/a

Form 43-a V.13

Date : 15.05.2025

Performed and approved by:

MMH