



SHOP PACKET - EASW

REFERENCE	BW35D100	ODR. QTY	720	RS: 2 + 1(QC TEST)	ISSUED DATE	03/02/2022
ITEM CODE	BW010007	PACK SIZE	24/BOX		LOT NO.	B20303
ITEM DESCRIPTION	Bactiguard Woundcare, 500ml (Cap Closure)	CUSTOMER	Bactiguard AB (Lifecyn)		MFG. DATE	03/02/2022
		ODR. NO	B004		EXP. DATE	28/01/2024
PREPARED BY	NAME : NUR SHAHIRA DATE : 03/02/2022	VERIFIED BY		NAME : RATNASEGARAN DATE : 03/02/2022	INT. ORDER	IO/CYN/060505/01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	07333330201551	UDI-DI NO. (2nd Packaging) - Carton	17333330201558			
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)07333330201551	(11)03022022	UDI-PI NO. (2nd Packaging) - Carton	(01)17333330201558	(11)03022022	
	(17)28012024	(10)B20303		(17)28012024	(10)B20303	

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS	
STOCK SOLUTION PREPARATION							
TIME START : DATE : TIME COMPLETE : DATE :	5:00 PM 08-02-22	723	723	Nil	Roshni (893)	Time 500 ITI 03HB080222082	
UDI PRINTING (Label/Box/Carton)							
TIME START : DATE : TIME COMPLETE : DATE :	1:45 PM 10-02-22	724	724	Nil	Roshni 789 10/02/2022	N/A	
SOLUTION FILLING & CAPPING							
TIME START : DATE : TIME COMPLETE : DATE :	8:48 AM 10-02-22	723	723	1	Farah (1051) Netra (1103)	Roshni 9:40AM 10/02/22	
LABELLING							
TIME START : DATE : TIME COMPLETE : DATE :	7:35 PM 11-02-22	723	723	Nil	Ranjana(110) Mandisha(112)	Roshni 8:30PM 11-2-22	N/A
PRINTING LOT NUMBER							
TIME START : DATE : TIME COMPLETE : DATE :	7:35 PM 11-02-22	723	723	Nil	Ranjana(110) Mandisha(112)	Roshni 8:30PM 11-2-22	N/A
CAP SEALING (Applicable for 1000mL)					NA		
TIME START : DATE : TIME COMPLETE : DATE :							
BOX PACKING & PRINTING (Applicable for 1000ml only)					NA		
TIME START : DATE : TIME COMPLETE : DATE :							
MANUAL UDI LABELLING (Applicable for 1000 mL & Bags only)					NA		
TIME START : DATE : TIME COMPLETE : DATE :							
FINAL CONTROL							
TIME START : DATE : TIME COMPLETE : DATE :	7:35 PM 11-02-22	723	723	Nil	Ranjana Mandisha	Roshni 8:38pm 11-2-22	N/A
CARTON PACK							
TIME START : DATE : TIME COMPLETE : DATE :	9:00 AM 14-02-22	30 ctn	30 ctn	Nil	FASLI(1084) RAKIB(1082)	Jinda 14/02/2022	8/8
UDI LABELLING							
TIME START : DATE : TIME COMPLETE : DATE :	9:00 AM 14-02-22	30 ctn	30 ctn	Nil	FASLI(1084)	Jinda 14/02/2022	Kyra 14/02/2022

QUANTITY PRODUCED	723 Vials
QUANTITY FOR QC / RETAIN SAMPLE	285+1 btl
SHIPMENT QUANTITY PCS / CTNS	720 Vials / 30 ctn Not 41/22
FINAL SHIPMENT DATE	
COMPLETE/ PARTIAL	COMPLETE PARTIAL

Checked by (PR), Signature : Name : RATNASEGARAN Date : 14/2/22	Approved by (QA), Signature : Name : Rohanita Chiman Date : 9/3/2022	Released by (QC), Signature : Name : MARTIN Designation : QC DEPT Date : 14/2/22 Stamp :
Remarks:		 RELEASED BACTIGUARD (SEA) SDN BHD QUALITY CONTROL

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CHECKLIST FOR LINE CLEARANCE OF
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)Doc. No QC-LC002
Rev. 00

Item Description	<i>Bactiguard woundcare 500 ml (cap closure)</i>		
Reference	<i>BW35WVO</i>		
Lot No.	<i>B20303</i>		

No.	Checklist	Yes	No	Performed by (Signature / Date)	Verified by QC (Signature / Date)	Remarks	Responsibility
1	Flush machine HD-01 with approximately 20L of RODI water & 10L of EASW solution before each production batch	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Kyudan</i> 10/02/22	<i>Kosuke</i> 10/02/22	N/A	Technician
2	All machine components which are directly in contact with the product materials are thoroughly cleaned and free from rust / dirt / dust and foreign particles						
i) Starwheel	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
ii) Nozzle	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
iii) Stopper Insertor	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
iv) Cap Dispenser	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
v) Cap Pusher	<input checked="" type="checkbox"/>	<input type="checkbox"/>					
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Cawong</i> 10/02/22	<i>Cawong</i> 10/02/22	N/A	Production
4	All finished goods, materials and rejected items related to previous lot are cleared and removed from working area	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Cawong</i> 10/02/22	<i>Cawong</i> 10/02/22	N/A	Production

Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bactiguard	Issue Date: 15/11/2021	Page: 1(3)
Document type: FORM	Doc Id: QC-IP002-09			

Item Description	<i>Bactiguard wound care 500 ml (exp closure)</i>
Reference / Lot No.	<i>BW35D100 / B20303</i>
Order Qty	<i>720</i>
Volume Specification	<i>515 ± 5 ml</i>

A. Filling Process

B. Labelling, Lot No., Manufacturing Date and Expiry Date Process

Sampling / Frequency	Label printing is clear and legible (inclusive of special printing when applicable)	Reference No, Lot No, Manufacturing Date and Expiry Date are corresponding to Shop	Correct Position of Labelling on Packaging	Correct UDI number printing on labelling (Product Code, Manufacturing Date,	Test Disposition	
					PASS	FAIL
10/10	✓	✓	✓	✓	✓	□
1/300	✓	✓	✓	✓	✓	□
1/300	✓	✓	✓	✓	✓	□
1/113	✓	✓	✓	✓	✓	□
	-	-	-	-	□	□
					□	□
					□	□
					□	□

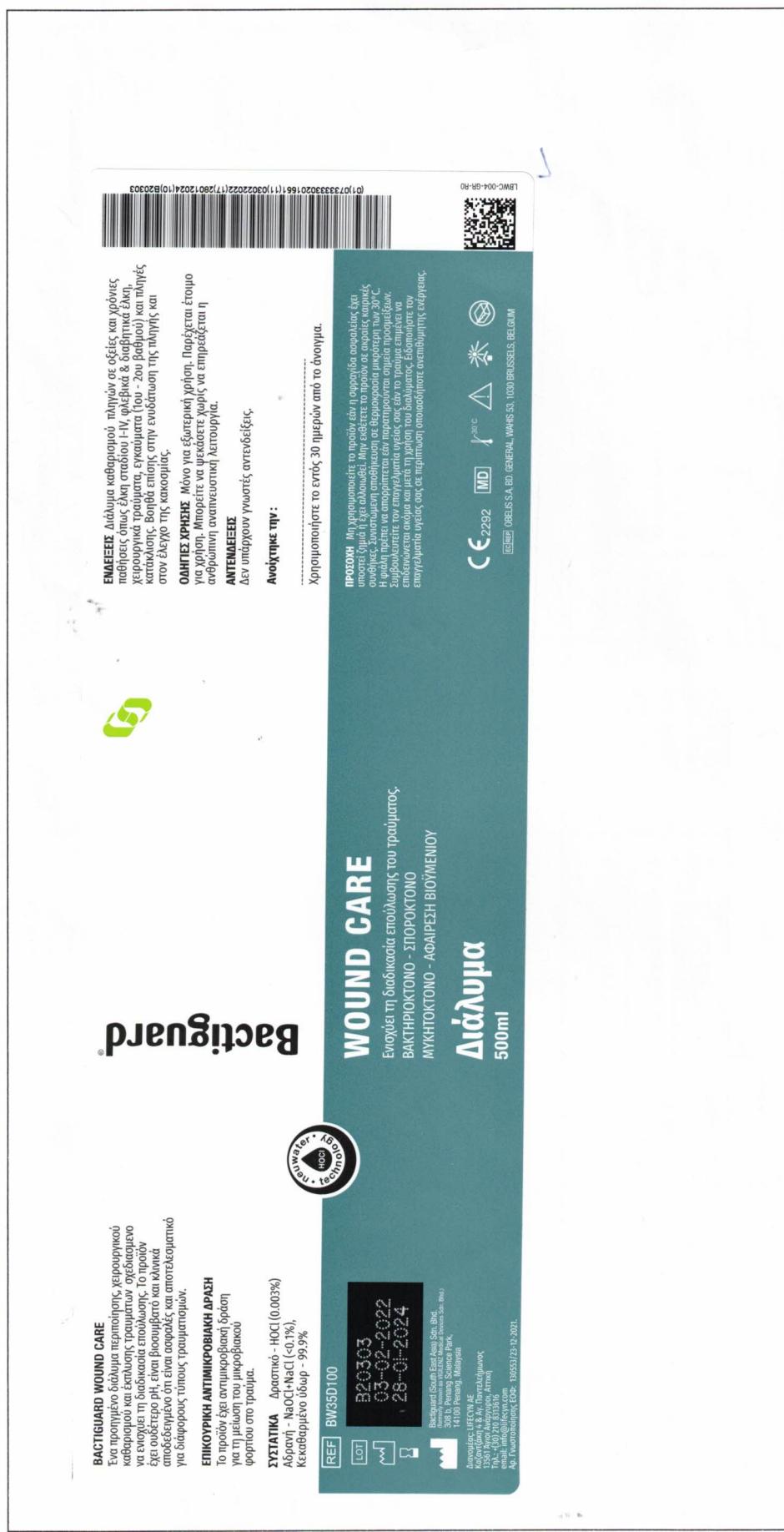
IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)
Document type:
FORM

C IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc id:	Bactiguard
Issue Date:	15/11/2021

Document type:
FORM

C. Attachment (First Printed Label)



Disposition of the Lot : PASS FAIL

Inspected by : Wach

Name

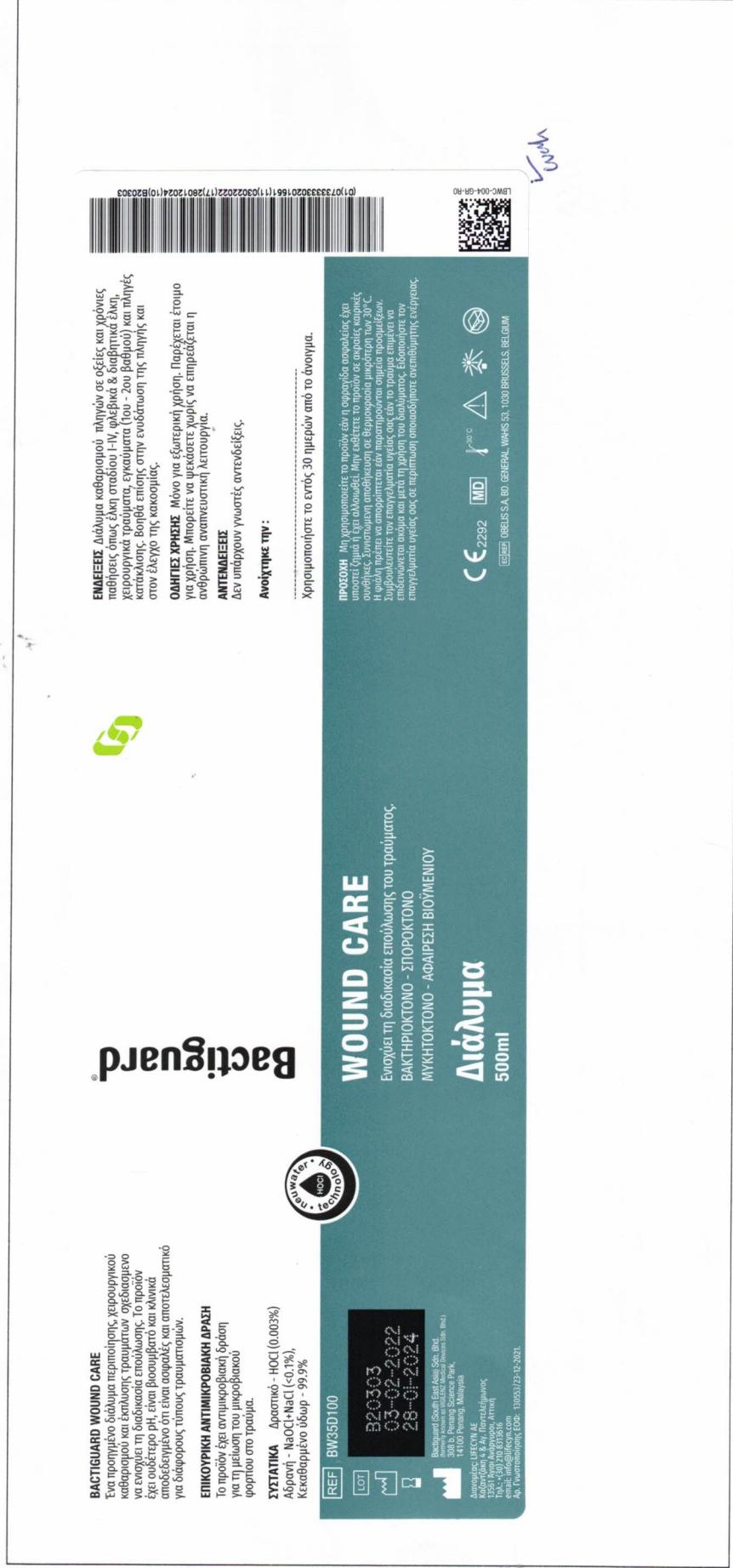
Date : 11.02.2022

Name

Date

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
Document type:	Doc Id:	Bactiguard	Issue Date:
FORM	QC-IP002-09	15/11/2021	Page: 3 (3)

D. Attachment (Last Printed Label)



Disposition of the Lot : PASS FAIL

Inspected by : W.W.

Name : W.W.

Date : 11.02.2024

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**FINAL CONTROL TEST REPORT -
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)**

ITEM DESCRIPTION :	Bottiglie vuoto 500ml	Doc. No.	QC-FC004
		Rev.	09

REFERENCE :	BLW 35 D100	QTY. PRODUCED (pcs) :	723
LOT NO. :	BLW 303	RETAIN SAMPLE QTY. (pcs) :	2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and clean printing of label.	S ₃ , 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	S ₃ , 0.15	80	0	1	80	0	pass
3	Proper sealing and no leaking.	S ₃ , 0.15	80	0	1	80	0	pass
4	Free from contamination / particle / foreign materials on product solution.	S ₃ , 0.15	80	0	1	80	0	pass
5	Correct volume filled (against reference sample).	S ₃ , 0.15	80	0	1	80	0	pass

Remarks : N/A

Inspected By : Moh
 Name : Moh Amin
 Date : 11/02/2022

Approved By : M A RTINI
 Name : M A RTINI
 Date : 11/02/2022

DATE :	09/02/2022
REF :	BW35D100
LOT NO. :	B20303

SHOP PACKET QTY (pes)	:	720
CUSTOMER	:	BACTIGUARD AB (LIFECYN)
LO. NO.	:	10/CYN/060505/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)		RECEIVED BY
								CONSUMPTION	RECEIVED	
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H0102220101	pes	723	723	723	723	✓ Cayane
2	P0100814	e Cap for 250ml/500ml HDPE Plastic Container - Bactiguard Woun	0	H020210601	pes	723	723	723	723	✓ Cayane
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pes	723	723	723	723	✓ Cayane
4		STOCK SOLUTION		03413080292091	ltr	375	375	375	375	✓ Cayane

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)
1	P0100892	LBWC-004-GR-R0 (500ML -Cap Closure- GREECE), VIGILENZ0144; 210MM X 71MM, IN ROLL, GLOSS WHITE BOPP; 4C + EYEMARK	LG07220201	724	#N/A
2				#N/A	
3				#N/A	
4				#N/A	
5				#N/A	
6				#N/A	
7				#N/A	

(3) OVER WRAPPING AND CARTON PACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (B.A.F)		H165211201	30
2	P0100680	500ml nesting short and long-		H065220101	30
3			#N/A		

(4) SPECIAL REQUIREMENT					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)		#N/A	
2				#N/A	

ISSUED BY (MM) :

Signature :

Name :

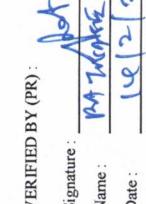
Date :

VERIFIED BY (PR) :

Signature :

Name :

Date :



Handwritten signatures for Verification and Receipt, including names and dates.

Title: OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD		 Bactiguard	
Document type: FORM		Doc ID: QC-OI001-04	Issue Date: 09/07/2022 Page: 1(2)

INSPECTION CRITERIA	REMARKS	
	QUANTITY CHECKED / CARTON	QUANTITY CARTON
PRODUCT NOT DAMAGED / DENT	✓	✓
CARTON NOT CRUMPLED	✓	✓
TEAR / DAMAGE	✓	✓
INFORMATION PACKAGING	✓	✓
REF. NO. & LOT NO.	✓	✓
Product Code, Manufacturing Date & Lot No., Date, Expiry Date & Lot No., Ref. No. & Lot No., Shop Packets)	✓	✓
NUMBER OF CARTON ON CARTON (UDI Number), Product Code, Manufacturing Date, Expiry Date & Lot No.)	✓	✓
PACKAGING INFORMATION	✓	✓
PRODUCT NOT DAMAGED / DENT	✓	✓
CARTON NOT CRUMPLED	✓	✓
TEAR / DAMAGE	✓	✓
INFORMATION PACKAGING	✓	✓
REF. NO.	LOT NO.	QTY (BXS / PCS / BTLS) / CARTON
14/02/2022	BW35V100	24-30
Bandage	Brood	1-30
	wound care	

Please print addition sheet if required

inspected by : Jordan Date : 14/03/2021
Name :
Date :

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Name _____ Date _____

K. Nalini
15/02/2022

Page

Title:	OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD		
Document type:	FORM		
	Doc ID: QC-OI001-04	Issue Date: 09/02/2022	Page: 2(2)

A. Attachment (Carton UDI label)

<h1>Bactiguard®</h1>	
PRODUCT : Bactiguard Woundcare, 500ml QUANTITY : 24 PCS	 (01)1733330201558(1)0302222211712801202410B20303 
Manufacturer: Bactiguard (South East Asia) Sdn Bhd (formerly known as VIGILENZ Medical Devices Sdn Bhd) 308b, Jalan Perindustrian Bukit Minyak 18, Penang Science Park, 14100 Penang, Malaysia. REF BW35D100 LOT B20303  28-01-2024	

*Only print this sheet for products with UDI

Inspected by : J. M. L.
 Name : J. M. L.
 Date : 14/02/2022

Page 2


Verified by
 Name : K. Nalinini
 Date : 15/02/2022

VIGILENZ®

**PRODUCT RELEASE TEST REPORT –
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)**

Doc No.	QC-PC001
Rev.	06

Description	BagGuard closure, 500ml Cap Closure	Reference No.	BW35D100	Date of Inspection	12/02/2022
	Lot No.	B20203		Sample Size	16H X 500 ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					Test Disposition (PASS / FAIL)
pH	ORP (mV)	FAC (ppm)	Spec: 95-140	Result	Instrument
Result	Instrument	Result	Instrument	Result	Instrument
7.18	OR-78	865	OR-67	111	OR-80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*

Disposition of the Lot : RELEASE ON-HOLD



Approved By : *Rajesh*
 Name : *K A RTINI*
 Date : *12/02/2022*

Analyzed By : *Rajesh*
 Name : *K A RTINI*
 Date : *12/02/2022*