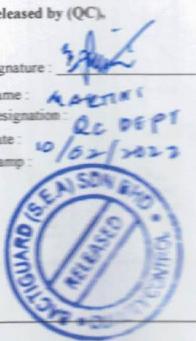


SHOP PACKET - EASW

REFERENCE	HW34E100	ODR. QTY (PCS)	900	RS(2) QC <i>12</i> <i>by</i> <i>8942</i>	ISSUED DATE	08/02/2022
ITEM CODE	H0100006	PACK SIZE	50/Box		LOT NO.	B20803
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Bottle Cap Closure)	CUSTOMER	VMD		MFG. DATE	08/02/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 08/02/2022	ODR. NO	B040		EXP. DATE	2024-02
		VERIFIED BY		NAME : RATNASEGARAN DATE : 08/02/2022	INT. ORDER	IO/VMD/080222/01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton			N/A	
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-PI NO. (2nd Packaging) - Carton			N/A	

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	7:00 PM 29-01-22 9:00 am 30-01-22	904	904	Nil	Kyandar 893	Wah 30.1.22
UDI PRINTING (Label/Box/Carton)						UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	3:30 PM 08-02-22 5:00 pm 08-02-22	904	904	Nir	Hawa (998)	Wah 5:00 PM 8.2.22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	3:30 PM 08-02-22 5:00 pm 08-02-22	904	898	6	I Canjana (790)	Wah 5:00 PM 8.2.22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	3:30 PM 08-02-22 5:00 pm 08-02-22	904	904	Nir	I Canjana (790)	Wah 5:00PM 8.2.22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	3:30 PM 08-02-22 5:00 pm 08-02-22	904	904	Nir	I Canjana (790)	Wah 5:10 PM 8.2.22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	8:00 AM 10-02-22 9:30 AM 10-02-22	18 eth	18 eth	NH1	FASU (1054) Rabin (1088)	Jinla 10/02/22 10/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 904 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 2+2 btl
 SHIPMENT QUANTITY PCS / CTNS : 900 Ltrs / 18 Ctns
 FINAL SHIPMENT DATE :
 COMPLETE/ PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>Nir</i> Name : <i>Nur Shahira</i> Date : <i>10/2/22</i>	Approved by (QA), Signature : <i>Jm8</i> Name : <i>Rohamiza Othman</i> Date : <i>10/2/2022</i>	Released by (QC), Signature : <i>SA</i> Name : <i>AZIZAH</i> Designation : <i>QC DEPT</i> Date : <i>10/02/2022</i> Stamp : <i>10/02/2022</i>
Remarks:		
		

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CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED GATES

Item Description	Hydrocyn Aqua, 250 ml (Bottle cap closure)
Reference	HCU34/E100
Lot No.	P-2022

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 EASWsolution before each production batch	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>T. A. S. D.</u> 08/02/22	<u>Wah</u> 8.2.22	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 checked="" 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"/>	<u>T. A. S. D.</u> 08/02/22	<u>Wah</u> 8.2.22	N/A	Technician
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"/>	<u>T. A. S. D.</u> 08/02/22	<u>Wah</u> 8.2.22	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	Hydroxyn Aqua, 250 ml (Bottle cap closure)		
Reference / Lot No.	HW34E100 / B20803		
Order Qty	900		
Volume Specification	255	±	5 ml

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	✓	✓	✓	✓	✓	□
1/294	✓	✓	✓	✓	✓	□
					□	□
					□	□
					□	□

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	
Document type: FORM	Doc Id: QC-IP002-09
 Bactiguard	Issue Date: 15/11/2021
C. <u>Attachment (First Printed Label)</u>	



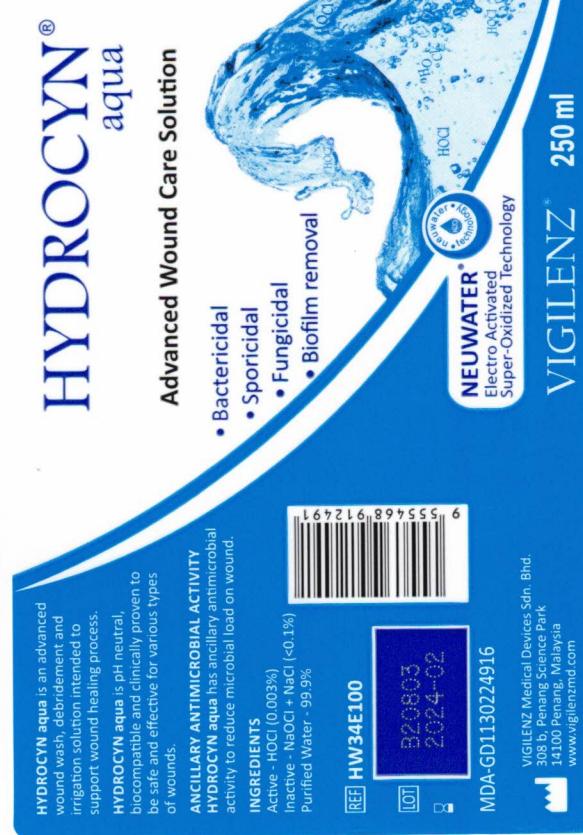
Disposition of the Lot:

PASS FAIL

Inspected by : Lush
Name : Lush arch
Date : 8-2-2022

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

D. Attachment (Last Printed Label)



INDICATION
HYDROCYN aqua is indicated as a wound wash, debridement and irrigation solution for acute and chronic wounds such as stage I-IV ulcers, venous stasis & diabetic ulcerations, post-surgery wounds, burns (1st-2nd degree) and bed sores. It also helps in moistening wound and control malodour.

DIRECTION FOR USE

For external use only. HYDROCYN aqua is supplied ready for use. It can be applied directly on body surface, skin and wounds. It can be misted or fogged without compromising human respiratory functions.

CAUTION

Do not use the product if the tamper proof seal is damaged or tempered with. Do not expose the product to extreme weather conditions. Stability is affected if the bottle is not stored or closed properly after use. HYDROCYN aqua is stable for 24 months from the date of manufacture (recommended storage below 30°C), if unopened and in its original packaging. Bottle to be discarded if signs of contaminants are seen. Consult your health care specialist if wound persist to deteriorate even after use of solution. Notify your health care specialist in case of any adverse effect.

CONTRAINDICATIONS

No Known contraindications.

LEH-260-FR0
159150008
EUROPEAN UNION
CE 2292
01/09/2028
VIGILENZ
250 ml
HOCl
NEUWATER®
Electro Activated
Super-Oxidized Technology
VIGILENZ®
250 ml
9 555468 912491
Date opened: _____
Use by 30 days of opening
VIGILENZ Medical Devices Sdn. Bhd.
308 b, Penang Science Park
14100 Penang, Malaysia
www.vigilenzmd.com

Woh Woh
8.7.22

Inspected by : Woh Woh
Name : Woh Woh
Date : 8.7.2022

Disposition of the Lot : PASS FAIL

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

ITEM DESCRIPTION :	Hydron Aqua, 250 ml
REFERENCE :	HU 34E100
LOT NO. :	B20803

QTY. PRODUCED (pcs) : 904

RETAIN SAMPLE QTY. (pcs) : 2

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

Remarks : N/A

Inspected By : Wah
Name : Wah Wah
Date : 8.2.2022

Approved By : M.A.P.T.M.I
Name : M.A.P.T.M.I
Date : 8/2/2022

DATE :	08/02/2022
REF :	HW34E100
LOT NO. :	B20803

SHOP PACKET QTY (pcs) : 900
 CUSTOMER : VMD (MALAYSIA)
 LO NO. : 10VMD/080222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H012210602	pcs	904	904	<i>Tanjung</i>
2	P0100283 <i>DCD</i>	#N/A	<i>Blue Cap</i>	H020210601	pcs	904	904	<i>Tanjung</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	904	904	
4		STOCK SOLUTION		<i>LBH20012004</i>	ltr			

(3) OVER WRAPPING AND CARTON PACK								
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pcs)	QTY ISSUED (pcs)	QTY CONSUMED (pcs)	RECEIVED BY
1	P0100566	DSN-H-009(A) - VIG-003-CTN-HYDROCYN 250ML(Cap Closure) Size: 330x330x 305mm, Mat: T180/M/T180 BA Flute		H060211102			18	<i>Malin</i>
2	P0100567	DSN-H-009(B) - VIG-901-ASY-HYDROCYN 250ml, NL & NS.312 x 90mm(4pics each), Mat:T150/T150 B Flute		H069211101			36	<i>Malin</i>
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute		H070211102			18	<i>Malin</i>
(4) SPECIAL REQUIREMENT								
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pcs)	QTY ISSUED (pcs)	QTY CONSUMED (pcs)	RECEIVED BY
1	P0100324	"SAMPLE NOT FOR SALE" Sticker - Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)				<i>#N/A</i>		
2						<i>#N/A</i>		

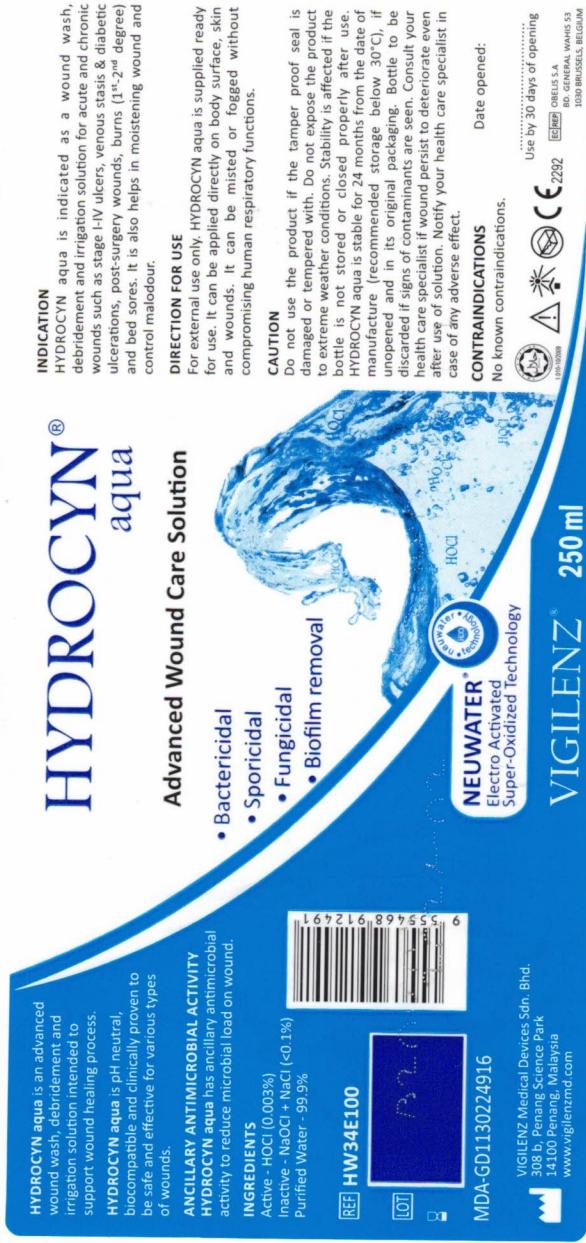
ISSUED BY (MM): *Lovin*
 Signature: _____
 Name: Lovin
 Date: 08/02/2022

VERIFIED BY (PR): *Azizah*
 Signature: *Azizah*
 Name: Azizah
 Date: 10/2/2022

Rework Instruction No. :						R1-PM12-22035				
Reference Code	HW34E100	Lot No.	B20803	Lot Quantity (pcs)	904	Quantity Affected (pcs)	6			
Process / Operation	Labelling & Printing Lot No.									
Type of Rework	Replace New label, Re-do the printing of the Lot number and Expiry date									
Reason for Rework	Misalignment printing of Lot No and Expiry date on labels									
Potential Adverse Effect (Filled by QA)	Scratch marks on bottles									
Training / Trainer (Tick whichever applicable)	<input type="checkbox"/>	Required	<input checked="" type="checkbox"/> / <input type="checkbox"/>	Not Required	Trainer : N/A					
Rework Operator	<i>1 Rayana</i>									
Required Tools	N/A									
Rework Step		Verified by (PR)	Inspection Details			Verified by (QAQC)				
1) Segregate the affected bottles		<i>1 Rayana 08/02/22</i>	All the bottles were verified			<i>✓ 8/2/22</i>				
2) Remove the damage labels (Misalignmant printing)		<i>1 Rayana 08/02/22</i>	All the labels were removed from the bottles			<i>✓ 8/2/22</i>				
3) Replace with new labels		<i>1 Rayana 08/02/22</i>	New labels were replaced			<i>✓ 8/2/22</i>				
4) Re-print again the Expiry date and Lot number at correct position		<i>1 Rayana 08/02/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>✓ 8/2/22</i>				
5) Proceed to Cap Sealing Process		<i>1 Rayana 08/02/22</i>	Verified in Cap Sealing process and complies with all the specifications			<i>✓ 8/2/22</i>				
Rework Disposition :										
Production had completed all the rework steps and proceed to Final Control process. QC had verified during all the rework steps and all complies with the specification.										
Prepared By : <i>Abhishek</i>	Name : MR.RATNA	Acknowledge By : <i>Martini</i>	Date: 08/02/2022	Approved By : <i>S. Jeevanend</i>	Date : 10/2/2022					

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide, 250ml (Bottle cap closure)	Reference No.	HWT100	Date of Inspection	10/02/2022
Lot No.	B00803	Sample Size	2 x 250 ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)				Test Disposition (PASS / FAIL)	
pH	ORP (mV)	FAC (ppm)	Spec:	Test Disposition (PASS / FAIL)	
Result	Instrument	Instrument	Result	Instrument	Instrument
Spec: 6.50 - 8.00	Spec: > 850	Spec: 95 - 140			
7.18	QCT-78	QCT-67	113	QC-80	pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Zyq
Name : MARTINI
Date : 10/2/2022

ON-HOLD

Approved By : DR
Name : BAKRY
Date : 10/2/22

