

23/2

SHOP PACKET - EASW

REFERENCE	HW3CE700	ODR. QTY (PCS)	4,500	RS(2) QC(5)	ISSUED DATE	14/02/2022
ITEM CODE	H010004	PACK SIZE	50/Box	LOT NO.	B21402	
ITEM DESCRIPTION	Hydrocyn Aqua, 100ml (Spray Mist)	CUSTOMER	VMD	MFG. DATE	14/02/2022	
PREPARED BY	NAME : NUR SHAHIRA <i>SMT</i> DATE : 14/02/2022	VERIFIED BY	ODR. NO. B063 NAME : RATNASEGARAN <i>NST</i> DATE : 14/02/2022	EXP. DATE	2024-02	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton	N/A	INT. ORDER	IO/VMD/110222/01	
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 :	8:20 PM 21-02-22 10:10 AM 22-02-22	4507	4507	Nil	Ryandean (893)	Poshni TANK 500L/T1 03HB210222050
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	9:46 AM 23-02-22 3:45 PM 23-02-22	4507	4507	Nil	Bashini (1117) Dewi Susi	Wah 3:45PM 23/2/22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	9:46 AM 23-02-22 3:45 PM 23-02-22	4507	4507	17	Bashini (1117) Dewi Susi	Wah 3:45PM 23/2/22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	9:46 AM 23-02-22 3:45 PM 23-02-22	4507	4507	Nil	Bashini (1117) Dewi Susi	Wah 3:45PM 23/2/22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :	10:15 AM 23-02-22 6:30 PM 23-02-22	4507	4507	Nil	Era (1122) Anti (1)	Wah 23/2/22
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :	4:00 PM 23-02-22 5:35 PM 23-02-22	4507	4507	Nil	Bashini (1117) Mira (1118)	Wah 8:35PM 23/2/22
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	4:00 PM 23-02-22 8:35 PM 23-02-22	4507	4507	Nil	Bashini (1117) Mira (1118)	Wah 8:35PM 23/2/22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	11:30 PM 24-02-22 3:30 PM 24-02-22	90 ctn	90 ctn	Nil	Vister (1123) Fasli (1054) Herdi (1053)	Linda 24/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 4507 Gls
 QUANTITY FOR QC / RETAIN SAMPLE : 2+5 btl
 SHIPMENT QUANTITY PCS / CTNS : 4500 Gls / 90 ctn
 FINAL SHIPMENT DATE :
 COMPLETE/ PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>NST</i>	Approved by (QA), Signature : <i>JM</i>	Released by (QC), Signature : <i>RTNI</i>
Name : <i>RATNASEGARAN</i> Date : 25/2/2022	Name : ROHANIZA OTHMAN Date : 25/2/2022	Signature : <i>RTNI</i> Name : MARTINI Designation : QC D2057 Date : 25/2/2022 Stamp :
Remarks:		 BACTIGUARD (SEA) SDN BHD RELEASED QUALITY CONTROL

VIGILENZ®

CHECKLIST FOR LINE CLEARANCE OF
ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Item Description	<i>Hydrogen Aqui 100m (spray mist)</i>
Reference	<i>HWW3CEH00</i>
Lot No.	<i>B201400</i>

		Doc. No	QC-LC002
		Rev.	00

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>Abdullah 293 23/02/2022</i>	<i>Prajy 23/2/22</i>	<i>ND</i>	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>Abdullah 293 23/02/2022</i>	<i>Prajy 23/2/22</i>	<i>ND</i>	Technician
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>1 Computer 23/02/22</i>	<i>Prajy 23/2/22</i>	<i>ND</i>	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>Computer 23/02/22</i>	<i>Prajy 23/2/22</i>	<i>ND</i>	Production

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

Item Description	<i>Hydrogen Aqua, 100 ml (spray mist)</i>	
Reference / Lot No.	HW3ET100/B31960	
Order Qty	4500	
Volume Specification	105	± 5 ml

A. Filling Process

Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition
10/10	105 ml	✓	✓	✓	✓	PASS
1/300	105 ml	✓	✓	✓	✓	FAIL
1/300	105 ml	✓	✓	✓	✓	FAIL
1/300	105 ml	✓	✓	✓	✓	FAIL
1/300	105 ml	✓	✓	✓	✓	FAIL
1/300	105 ml	✓	✓	✓	✓	FAIL
1/300	105 mL	✓	✓	✓	✓	FAIL
1/300	105 mL	✓	✓	✓	✓	FAIL

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
10/10	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL

Title:

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

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Bactiguard

Item Description	<i>Hydrogen Peroxide, 10% (spray mist)</i>	
Reference / Lot No.	<i>Hu3c Epo / B-1402</i>	
Order Qty	<i>4500</i>	
Volume Specification	<i>105</i>	<i>± 5 ml</i>

A. Filling Process

Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed	Test Disposition
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>105 mL</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

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
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>
<i>1/300</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>	<i>✓</i>

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Document type: FORM	Doc Id: QC-IP002-09			

Item Description	Hydrocyn Aque, 100ml (spray mist)		
Reference / Lot No.	HWO3C E700 / B21402		
Order Qty	4500 - 4500		
Volume Specification	105	±	5 ml

A. Filling Process

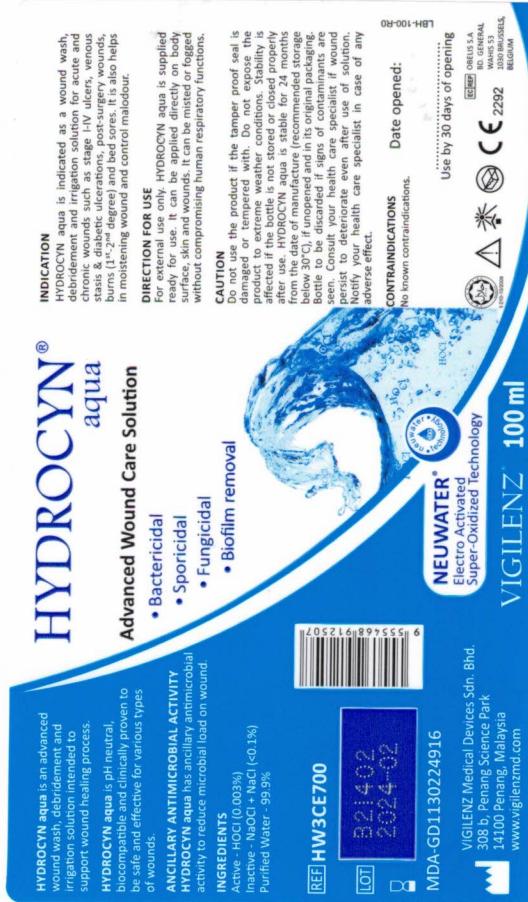
B. Labelling, Lot No. Manufacturing Date and Expiry Date Process

Title:

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

Document type:
FORM

C. Attachment (First Printed Label)



Bastiguard

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B21402
2024-02

✓ 3/11/21
✓ 3/11/21

HYDROCYN® aqua
Advanced Wound Care Solution

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 burns & fistula, decubitus, post-surgery wounds, burns, 1st-2nd degree abrasions and lacerations. 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 tampered 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 if recommended storage below 30°C. If unopened and correctly stored, bottle to be discarded if signs of contamination 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.

Use by 30 days of opening

REF HW3CE700
MDA-GD1130224916
VIGILENZ Medical Devices Sdn. Bhd.
308 b, Penang Science Park
14100 Penang, Malaysia
www.vigilenzmd.com

NEUWATER®
Electro Activated
Super-Oxidized Technology

VIGILENZ 100 ml

1067316-9915556

2024-02
LOT

Disposition of the Lot :

PASS FAIL

Inspected by : *Roly*

Name : *Romy*

Date : *23/11/21*

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D. Attachment (Last Printed Label)



Inspected by : Woh
 Name : Woh Woh
 Date : 23/10/2022

Disposition of the Lot : PASS FAIL

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No. QC-FC004
ITEM DESCRIPTION	Hydrogen Peroxide, 100 mL		Rev. 09

REFERENCE : HVO3CE700

LOT NO. : B21402

QTY. PRODUCED (pcs) : 1604

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.	S3, 0.15	80	0	1	80	0	0	pass
2	Free from contamination, deformed or damaged on packaging.	S3, 0.15	80	0	1	80	0	0	pass
3	Proper sealing and no leaking.	S3, 0.15	80	0	1	80	0	0	pass
4	Free from contamination / particle / foreign materials on product solution.	S3, 0.15	80	0	1	80	0	0	pass
5	Correct volume filled (against reference sample).	S3, 0.15	80	0	1	80	0	0	pass

Remarks : N/A

Approved By : Eduard
 Name : MARTIN
 Date : 23/2/2022

Inspected By : Umesh
 Name : Umesh
 Date : 23/2/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE :	16/02/2022
REF :	HW3CE700
LOT NO. :	B21402

SHOP PACKET QTY (pes) : 4500
 CUSTOMER : VMD (MALAYSIA)
 LO NO. : IOVMD/110222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	RECEIVED BY
1	P0100288	100ML HDPE BOTTLE	(NATURAL COLOUR WITH VIGILENZ LOGO)	H075211201	pes	4507	4507	4507	<i>Amelia</i>
2	P0100287	JQ-24A-PP	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP. PP, TUBE:90mm	H018200701	pes	4507	4507	4507	<i>Amelia</i>
3	N/A	STOCK SOLUTION	N/A	03/HB21022020	ltr	473	473	473	<i>Amelia</i>

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capseal (For 100ml /250ml Hydrocyn) - Size: 47 x 0.04 x 55 mm (I/C+P)	H019210901	4508	<i>Amelia</i>
2	P0100640	LBH-100-R0 - Hydrocyn Aqua 100ml Spray Mist Label, Size: 120mm x 70mm , Material : White PP	L187220103	4508	<i>Amelia</i>
3	P0100639	100ml Hydrocyn Box (Printed) - Material : ArtCard S Coated 300gsm, Size : 40mmx40mmx148mm	H020210901	4508	<i>Amelia</i>

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100324	"SAMPLE NOT FOR SALE" Sticker	Size: 35mm x 18mm, Material: Transparent PE, Colour: Red (2 layers)		100	<i>Amelia</i>
2		#N/A	#N/A		0	

(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H		H164220101	90	<i>Amelia</i>
2	P0100682	100ml LAYER PAD-		H043211202	810	<i>Amelia</i>

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H		H164220101	90	<i>Amelia</i>
2	P0100682	100ml LAYER PAD-		H043211202	810	<i>Amelia</i>

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H		H164220101	90	<i>Amelia</i>
2	P0100682	100ml LAYER PAD-		H043211202	810	<i>Amelia</i>

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H		H164220101	90	<i>Amelia</i>
2	P0100682	100ml LAYER PAD-		H043211202	810	<i>Amelia</i>

NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100678	100ml Hydrocyn Aqua Carton-440L X 220W X 156H		H164220101	90	<i>Amelia</i>
2	P0100682	100ml LAYER PAD-		H043211202	810	<i>Amelia</i>

ISSUED BY (MM) :

Signature : *Amelia*
 Name : LOVIN
 Date : 16/02/2022

VERIFIED BY (PR) :

Signature : *Amelia*
 Name : KARUNSE ORAH
 Date : 25/2/2022

VIGILENZ®

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

		Doc No.	QC-PC007
		Rev.	06

Description	Hydrogen Peroxide, 100mL (spray mist)	Reference No.	Hw3CE700	Date of Inspection	25/2/2022
Lot No.	B21402	Sample Size	500mL		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH		ORP (mV)	FAC (ppm)		Test Disposition (PASS / FAIL)
Spec: 6.50 - 8.00		Spec: +/- 250	Spec: 95 - 140		
Result	Instrument	Result	Instrument	Result	Instrument
7.25	Qc-7B	860	Qc-67	118	Qc-80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/r

Disposition of the Lot : RELEASE ON-HOLD



Approved By : Ast
 Name : K.Nairi
 Date : 25/02/2022

Analyzed By : Eugene
 Name : M.R.Tan
 Date : 25/02/2022