

19/2

SHOP PACKET - EASW

REFERENCE	HW3CE700	ODR. QTY (PCS)	4,500	RS(2) QC(5)	ISSUED DATE	14/02/2022
ITEM CODE	H0100004	PACK SIZE	50/Box	LOT NO.	B21401	
ITEM DESCRIPTION	Hydrocyn Aqua, 100ml (Spray Mist)	CUSTOMER	VMD	MFG. DATE	14/02/2022	
PREPARED BY	NAME : NUR SHAHIRA <i>Sgt</i> DATE : 14/02/2022	VERIFIED BY	NAME : RATNASEGARAN <i>Ad</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	IQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	8:30 AM 16-02-22 10:15 AM 17-02-22	4507	4507	Nil	Kyendan (893)	<i>Liet</i> 19/02/22 03HB16022020111
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :	8:50 AM 19-02-22 3:30 PM 19-02-22	4507	4507	Nil	Aye (884)	<i>Liet</i> 19/02/22 NP
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	8:50 AM 19-02-22 3:30 PM 19-02-22	4507	4507	Nil	Kyu (887)	<i>Liet</i> 19/02/22 -17 labels rejected replaced with new label
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	8:50 AM 19-02-22 3:30 PM 19-02-22	4507	4483	17	Kyu (887)	<i>Liet</i> 19/02/22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	8:50 AM 19-02-22 3:30 PM 19-02-22	4507	4507	Nil	Kyu (887)	<i>Liet</i> 19/02/22 NP
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :	10:20 AM 19-02-22 3:45 PM 19-02-22	4507	4507	Nil	Roshini (757) Khin (647)	<i>Roshini</i> 3:45PM 19/02/22 NP
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :	11:00 AM 19-02-22 5:00 PM 19-02-22	4507	4507	Nil	Mayu (848) Kali (1078)	<i>Roshini</i> 5:00PM 19/02/22 NP
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 :	3:30 PM 17-02-22 11:30 AM 21-02-22	4507	4507	Nil	Kali (1078) Aye (884)	<i>Roshini</i> 21/02/22 11:30AM NP
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	12:00 PM 21-02-22 4:00 PM 21-02-22	90 Ctn	90 Ctn	Nil	RABIN (1088) VISITER (1088)	<i>Nurin</i> 21/2/22 <i>Ky</i> 21/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED	4507 btl
QUANTITY FOR QC / RETAIN SAMPLE	20st 5btl
SHIPMENT QUANTITY PCS / CTNS	4,800 4tr / 90ctn
FINAL SHIPMENT DATE	
COMPLETE/ PARTIAL	COMPLETE

Checked by (PR), Signature : <i>Abd</i> Name : RATNASEGARAN Date : 21/2/22	Approved by (QA), Signature : <i>Jm</i> Name : Rohamza Othman Date : 22/2/2022	Released by (QC), Signature : <i>Sh</i> Name : MARTINI Designation : QC DEPT? Date : 21/2/22 Stamp :
Remarks:		



VIGILENZ®		CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No	QC-LC002		
Item Description				Rev.	00		
Reference	HYDROCYN Aqua Econol Spray Mist						
Lot No.	HW3CE700 / B01401						
Lot No.	4507						

Item Description	HYDROCYN Aqua Econol Spray Mist		
Reference	HW3CE700 / B01401		
Lot No.	4507		

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"/>	 893 19/02/2022	 19/02/2022	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			 893 19/02/2022	 19/02/2022	N/A	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"/>	 19/02/22	 19/02/22	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"/>	 19/02/22	 19/02/22	N/A	Production

Title:

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

Document type:

FORM

Doc Id:

QC-IP002-09

Bractiguard

Page:
1(3)

Item Description	Hypochlorite Aqua 100ml (Spray mist)
Reference / Lot No.	HW 3CE700 / B91401
Order Qty	Lsf. 40 450 ml
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
1010	110 mL	✓	✓	✓	✓	PASS
11300	110 mL	✓	✓	✓	✓	FAIL
11300	110 mL	✓	✓	✓	✓	FAIL
11300	110 mL	✓	✓	✓	✓	FAIL
11300	110 mL	✓	✓	✓	✓	FAIL
11300	110 mL	✓	✓	✓	✓	FAIL
11300	110 mL	✓	✓	✓	✓	FAIL
11300	110 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
1010	✓	✓	✓	✓	FAIL
11300	✓	✓	✓	✓	FAIL
11300	✓	✓	✓	✓	FAIL
11300	✓	✓	✓	N/A	FAIL
11300	✓	✓	✓	✓	FAIL
11300	✓	✓	✓	✓	FAIL
11300	✓	✓	✓	✓	FAIL

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

Item Description	Hypochlorine Aqua 100ml (Spray mist)
Reference / Lot No.	HUSCE700 / B21401
Order Qty	4507
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
1/300	100 mL	✓	✓	✓	✓	PASS
1/300	100 mL	✓	✓	✓	✓	FAIL
1/300	100 mL	✓	✓	✓	✓	FAIL
1/300	100 mL	✓	✓	✓	✓	FAIL
1/300	100 mL	✓	✓	✓	✓	FAIL
1/300	100 mL	✓	✓	✓	✓	FAIL
1/300	100 mL	✓	✓	✓	✓	FAIL
1/300	100 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
1/300	✓	✓	✓	✓	✓
1/300	✓	✓	✓	✓	✓
1/300	✓	✓	✓	✓	✓
1/300	✓	✓	✓	N/A	✓
1/300	✓	✓	✓	✓	✓
1/300	✓	✓	✓	✓	✓
1/300	✓	✓	✓	✓	✓

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

Item Description	Hypocyclo N Aqua	100mL	(Spray Mist)
Reference / Lot No.	H03CE700	/ 801401	
Order Qty	450.0		
Volume Specification	10.5	± 5	ml

A. Filling Process

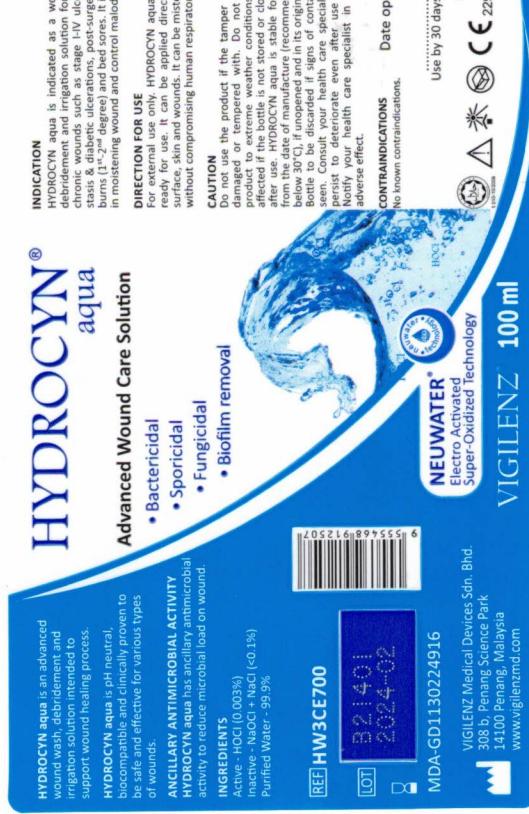
B. Labelling, Lot No. Manufacturing Date and Expiry Date Process

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

C. Attachment (First Printed Label)

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

Doc Id:	QC-IP002-09	Issue Date:	15/11/2021	Page:	2(3)
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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 a general wash, HYDROCYN aqua is supplied in a general bottle. It can be applied directly on the wound 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 if tempered. If no tamper proof seal is affected by 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. Inform your health care specialist in case of any adverse effect.

CONTRAINDICATIONS

No known contraindications.

Date opened:

Use by 30 days of opening

LBH-100-PR0

REF: HW3CE700

LOT: B21401

2024-02

MDA-GD1130224916

VIGILENZ Medical Devices Sdn. Bhd.

308b, Penang Science Park

14100 Penang, Malaysia

www.vigilenzmd.com

Disposition of the Lot :

PASS FAIL

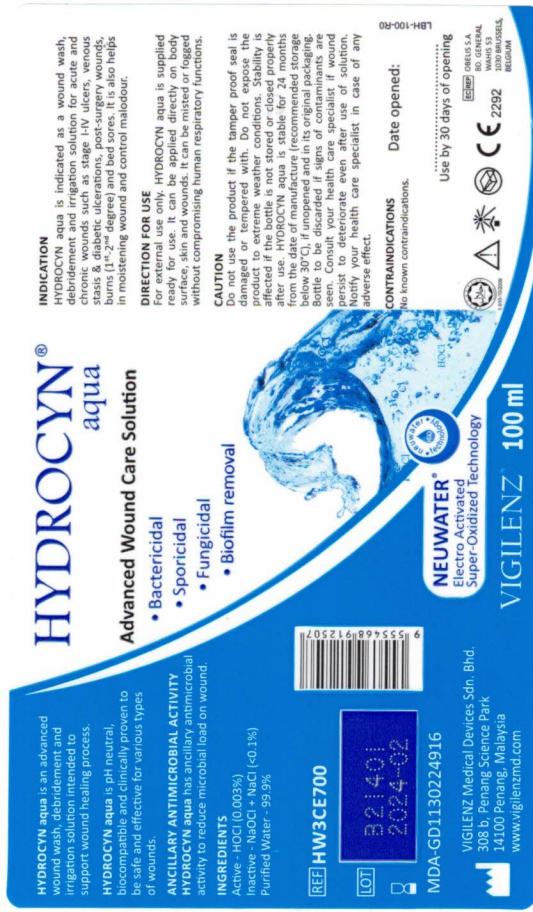
Inspected by : Lia

Name : Zin May

Date : 19/03/2022

Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bactiguard	Page: 3(3)
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D. Attachment (Last Printed Label)



Inspected by : Fat
Name : Zin Mar Aye
Date : 19/03/2022

PASS

Disposition of the Lot:

VIGILENZ®

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

ITEM DESCRIPTION :	<i>Hydrogen Aqua, 100ml (spraym)</i>	Doc. No.	QC-FC004
REFERENCE :	<i>Hw3Gf00</i>	Rev.	09

ITEM DESCRIPTION :

Hydrogen Aqua, 100ml (spraym)

REFERENCE :

Hw3Gf00

LOT NO. :

B21401

QTY. PRODUCED (pes) :
1501

RETAIN SAMPLE QTY. (pes) :
3

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Accept	Reject	Results	Status
				Accept	Reject				
1	Legible and clean printing of label.	<i>S2, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>	<i>pass</i>
2	Free from contamination, deformed or damaged on packaging.	<i>S3, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>	<i>pass</i>
3	Proper sealing and no leaking.	<i>S3, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>	<i>pass</i>
4	Free from contamination / particle / foreign materials on product solution.	<i>S3, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>	<i>pass</i>
5	Correct volume filled (against reference sample).	<i>S3, 0.15</i>	<i>80</i>	<i>0</i>	<i>1</i>	<i>80</i>	<i>0</i>	<i>pass</i>	<i>pass</i>

Remarks :

N/A

Inspected By

Raj

Name

Roshni

Date

21/09/21

Approved By

Raj

Name

RAVINI

Date

21/09/21

RAW MATERIAL LOADING FORM (RMLF)

DATE :	16/02/2022
REF :	HW3CE700
LOT NO. :	B21401

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

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		RECEIVED BY
							ISSUED	CONSUMPTION	
1	P0100288	100ML HDPE BOTTLE	(NATURAL COLOUR WITH VIGILENZ LOGO)	H075211201	pcs	4507	4507	4507	<u>ICayano</u>
2	P0100287	JQ-24A-PP	24/410 MIST SPRAYER, RIBBED, 316 SPRING, HALF CAP, PP, TUBE:90mm	H018200701	pcs	4507	4507	4507	<u>ICayano</u>
3	N/A	STOCK SOLUTION	N/A	63HB16022244	ltr	473	473	473	<u>ICayano</u>

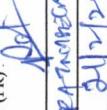
(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	(3) OVER WRAPPING AND CARTON PACK					
						NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100265	Secure Capsel (For 100ml /250ml Hydrocy) - Size: 47 x 0.04 x 55 mm (1C-P)	H019210901	4508	<u>ICayano</u>	1	P0100678	100ml Hydrocy Aqua Carton-440L X 220W X 156H	H164220101	90	<u>ICayano</u>
2	P0100640	LBH-100-R0 - Hydrocyn Aqua 100ml Spray Mist Label, Size : 120mm x 70mm, Material : White PP	L187220103	4508	<u>ICayano</u>	2	P0100682	100ml LAYER PAD-	H043211202	810	<u>ICayano</u>
3	P0100639	100ml Hydrocy Box (Printed) - Material : ArtCard1S Coated 300gsm, Size : 40mmx40mmx148mm	H020210901	4508	<u>ICayano</u>						
4		#N/A									
5		#N/A									
6		#N/A									
7		#N/A									

ISSUED BY (MM) :


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

VERIFIED BY (PR) :


 Signature :
 Name : PATRICIA
 Date : 21/2/22

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide 100 mL	Reference No.	Hw3CE700	Date of Inspection	21/21/22
spray mist	Lot No.	B21401		Sample Size	5 mL x 100 mL

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	FAC (ppm)	Test Disposition (PASS / FAIL)		
Spec:	Spec: > 850	Spec: 95 - 140			
Result	Instrument	Result	Instrument	Result	Instrument
7.19	ORC-78	865	ORC-67	111	ORC - 80
					Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Sander
Name : Sander Rose
Date : 21/21/22

Approved By : *[Signature]*
Name : Narin
Date : 21/21/22



Rework Instruction No. : R1-PM12-22043						
Reference Code	HW3CE700	Lot No.	B21401	Lot Quantity (pcs)	4507	
Quantity Affected (pcs)	17					
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"/> Not Required	Trainer : N/A			
Rework Operator	14yu					
Required Tools	N/A					
Rework Step		Verified by (PR)	Inspection Details			Verified by (QAQC)
1) Segregate the affected bottles		14yu 19/02/22	All the bottles were verified			14yu 19/02/22
2) Remove the damage labels (Misalignment printing)		14yu 19/02/22	All the labels were removed from the bottles			14yu 19/02/22
3) Replace with new labels		14yu 19/02/22	New labels were replaced			14yu 19/02/22
4) Re-print again the Expiry date and Lot number at correct position		14yu 19/02/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			14yu 19/02/22
5) Proceed to Cap Sealing Process		14yu 19/02/22	Verified in Cap Sealing process and complies with all the specifications			14yu 19/02/22
Rework Disposition :						
Prepared By :	Acknowledge By :		Approved By :			
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI		Name : MR.JEEVANEND			
Date: 19/02/2022	Date: 21/02/22		Date : 20/02/22			

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing

