

22/2

## SHOP PACKET - EASW

REFERENCE	HW34E100	ODR. QTY (PCS)	4,000	RS(2) QC(2)	ISSUED DATE	14/02/2022
ITEM CODE	H010006	PACK SIZE	50/Box		LOT NO.	B21406
ITEM DESCRIPTION	Hydrocyn Aqua, 250ml (Bottle Cap Closure)	CUSTOMER	VMD		MFG. DATE	14/02/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 14/02/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 14/02/2022		EXP. DATE	2024-02
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton			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
<b>STOCK SOLUTION PREPARATION</b>						
TIME START :	8:20 PM					
DATE :	21-02-22	4004	4004	NIL	Wah	Tank 1000L/T7 03HB210222051
TIME COMPLETE :	8:15 AM				21.2.22	
DATE :	21-02-22					
<b>UDI PRINTING (Label/Box/Carton)</b>						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						UDI NOT REQUIRED FOR THIS LOT
<b>SOLUTION FILLING &amp; CAPPING</b>						
TIME START :	10:30PM					
DATE :	03-02-22	4004	3997	7	MIRA (1118) DEVI (1126)	Wah 22.2.22
TIME COMPLETE :	5:35 PM					- 7 Bottles reject replace with new Bottles
DATE :	22-02-22					
<b>LABELLING</b>						
TIME START :	10:30PM					
DATE :	03-02-22	4004	4002	2	Bashini (1117) MIRA (1118)	Wah 22.2.22
TIME COMPLETE :	5:35 PM					- 2 Label reject replace with new Label
DATE :	22-02-22					
<b>PRINTING LOT NUMBER</b>						
TIME START :	10:30PM					
DATE :	03-02-22	4004	4004	NIL	Bashini (1117) MIRA (1118)	Wah 22.2.22
TIME COMPLETE :	5:35pm					
DATE :	22-02-22					N/A
<b>CAP SEALING (Applicable for 100mL)</b>						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						
<b>BOX PACKING &amp; PRINTING (Applicable for 100ml only)</b>						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						
<b>MANUAL UDI LABELLING (Applicable for 100 mL &amp; Bags only)</b>						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						UDI NOT REQUIRED FOR THIS LOT
<b>FINAL CONTROL</b>						
TIME START :	12:30PM					
DATE :	03-02-22	4004	4004	NIL	Bashini (1117) MIRA (1118)	Wah 5:40PM 22.2.22
TIME COMPLETE :	5:35 PM					
DATE :	22-02-22					N/A
<b>CARTON PACK</b>						
TIME START :	7:00PM					
DATE :	03-02-22	80 ctn	80 ctn	NIL	Manju (846) Vister (1123) Jchus (1122)	Jindas 28/02/2022 24/02/2022
TIME COMPLETE :	9:30 AM					
DATE :	25-02-22					
<b>UDI LABELLING</b>						
TIME START :						
DATE :						
TIME COMPLETE :						
DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED :

4004 btl

QUANTITY FOR QC /  
RETAIN SAMPLE :

2+2 btl

SHIPMENT QUANTITY  
PCS / CTNS :

10000 btl / 80 ctn

FINAL SHIPMENT DATE :

[REDACTED]

COMPLETE/ PARTIAL :

COMPLETE PARTIAL

Checked by (PR),

Signature :

Abd

Name : RAPNAKUMAR  
Date : 25/2/2022

Approved by (QA),

Signature :

fmg

Name : Rohamda Othman  
Date : 25/2/2022

Released by (QC),

Signature :

N. S. PATINI

Name : QC DEPT  
Designation : Date : 25/2/2022

Stamp :



VIGILENZ®		CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)			
		Doc. No	QC-LC002		
Item Description	Hydrogen Peroxide 250 ml, C-Bottle cap closure )	Rev.	00		
Reference	HUW34E100				
Lot No.	B21406				

Item Description	Hydrogen Peroxide 250 ml, C-Bottle cap closure )
Reference	HUW34E100
Lot No.	B21406

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"/>	<u>Wah</u> <u>893</u> <u>22/02/2022</u>	<u>N/A</u>		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			<u>Wah</u> <u>893</u> <u>22/02/2022</u>	<u>N/A</u>		Technician
	i) Starwheel	<input type="checkbox"/>	<input type="checkbox"/>				
	ii) Nozzle	<input type="checkbox"/>	<input type="checkbox"/>				
	iii) Stopper Insertor	<input type="checkbox"/>	<input type="checkbox"/>				
	iv) Cap Dispenser	<input type="checkbox"/>	<input type="checkbox"/>				
	v) Cap Pusher	<input 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>Wah</u> <u>22/02/22</u>	<u>N/A</u>		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"/>	<u>Wah</u> <u>22/02/22</u>	<u>N/A</u>		Production

Title:

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

Document type:  
FORMDoc Id:  
QC-IP002-09Issue Date:  
15/11/2021Page:  
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Item Description	Hydrocyn Aquus, 260 mL (Bottle cap closure)
Reference / Lot No.	Hlu34E100 / B21406
Order Qty	4000
Volume Specification	255 ± 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	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS
1/300	260 mL	✓	✓	✓	✓	PASS

**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	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS
1/300	✓	✓	✓	✓	PASS



Item Description	<i>Hydrogen Peroxide, 250ml (Bottle cap closure)</i>	
Reference / Lot No.	HWE34E100	/ B21406
Order Qty	4000	
Volume Specification	255	± 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	260 mL	↙	↙	↙	↙	PASS
1/300	260 mL	↙	↙	↙	↙	FAIL
1/300	260 mL	↙	↙	↙	↙	FAIL
1/300	260 mL	↙	↙	↙	↙	FAIL
1/300	260 mL	↙	↙	↙	↙	FAIL
1/300	260 mL	↙	↙	↙	↙	FAIL
1/300	260 mL	↙	↙	↙	↙	FAIL
1/394	260 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	↙	↙	↙	↙	FAIL
1/300	↙	↙	↙	↙	FAIL
1/300	↙	↙	↙	↙	FAIL
1/300	↙	↙	↙	↙	FAIL
1/300	↙	↙	↙	↙	FAIL
1/300	↙	↙	↙	↙	FAIL
1/394	↙	↙	↙	↙	FAIL

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Item Description	
Reference / Lot No.	
Order Qty	
Volume Specification	± ml

#### A. Filling Process

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

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**C. Attachment (First 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 (1<sup>st</sup>, 2<sup>nd</sup> degree) and bed sores. It is 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.

Date opened: \_\_\_\_\_  
Use by 30 days of opening  
REF: 1100-0000  
CE 2292  
ORLELSA S.A.  
BD GENERAL WATIN 53  
1030 BRUSSELS, BELGIUM  
LBBH-250-R0

Disposition of the Lot :  PASS  FAIL

FAIL

Inspected by : Luck

Name : Luck wdh

Date : 22/02/2022

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



Inspected by : Lew  
Name : Lew Lew  
Date : 22/10/2022

Disposition of the Lot :  PASS  FAIL

VIGILENZ®

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

ITEM DESCRIPTION : Hydrogen Aqua, 250 mLREFERENCE : HU34 E100LOT NO. : B21406

QTY. PRODUCED (pcs) :

RETAIN SAMPLE QTY. (pcs) :

4004

2

Doc. No.	QC-FC004
Rev.	09

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

Inspected By : lukh  
 Name : lukh lukh  
 Date : 22.02.2022

Approved By : Edgardo  
 Name : MARTINI  
 Date : 22/2/2022

DATE :	16/02/2022
REF :	HW34E100
LOT NO. :	B21406

SHOP PACKET QTY (pes) : 4000  
 CUSTOMER : VMD (MALAYSIA)  
 I.O NO. : IOMD/110222/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100244	250ml HDPE Round Container (Natural)	(To be used with blue/black/white colour cap)	H01210602	pcs	4004	4004	4004	1 (Any 4 quo)
2	P01002813	#N/A	#N/A	H020210601	pcs	4004	4004	4004	1 (Any 4 quo)
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210401	pcs	4004	4004	4004	1 (Any 4 quo)
4		STOCK SOLUTION		O3H021022051	ltr	1041	1041	1041	1 (Any 4 quo)

## (2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)	RECEIVED BY
1	P0100642	LBH-250-RHydrocyn Aqua 250ml Cap Closure, Size : 170mm x 77mm, Material : White PP	L184211002	4005	1 (Any 4 quo)
2		#N/A			
3		#N/A			
4		#N/A			
5		#N/A			
6		#N/A			
7		#N/A			

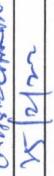
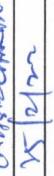
## (3) OVER WRAPPING AND CARTON PACK

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	Q'TY REQUIRED (pes)	RECEIVED BY
1	P0100566	DSN-H-009(A) - VIG-003-CTN-HYDROCYN 250ML(Cap Closure), Size: 330x330x 305mm, Mat: T180/M/180 BA Flute	H060211102	80	males
2	P0100567	DSN-H-009(B) - VIG-901-ASY_HYDROCYN 250ml, NL & NS:312 x 90mm(4pes each), Mat:T150/T150 B Flute	H069211101	160	males
3	P0100568	DSN-H-009(C) - VIG-901-ASY-HYDROCYN 250ml(Layer pad), Size: 312 x 312mm, Mat: T150/T150 B Flute	H070211102	80	males

## (4) SPECIAL REQUIREMENT

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

ISSUED BY (MM) :   
 Signature :   
 Name : LOVIN  
 Date : 16/02/2022

VERIFIED BY (PR) :   
 Signature :   
 Name :   
 Date : 16/02/2022

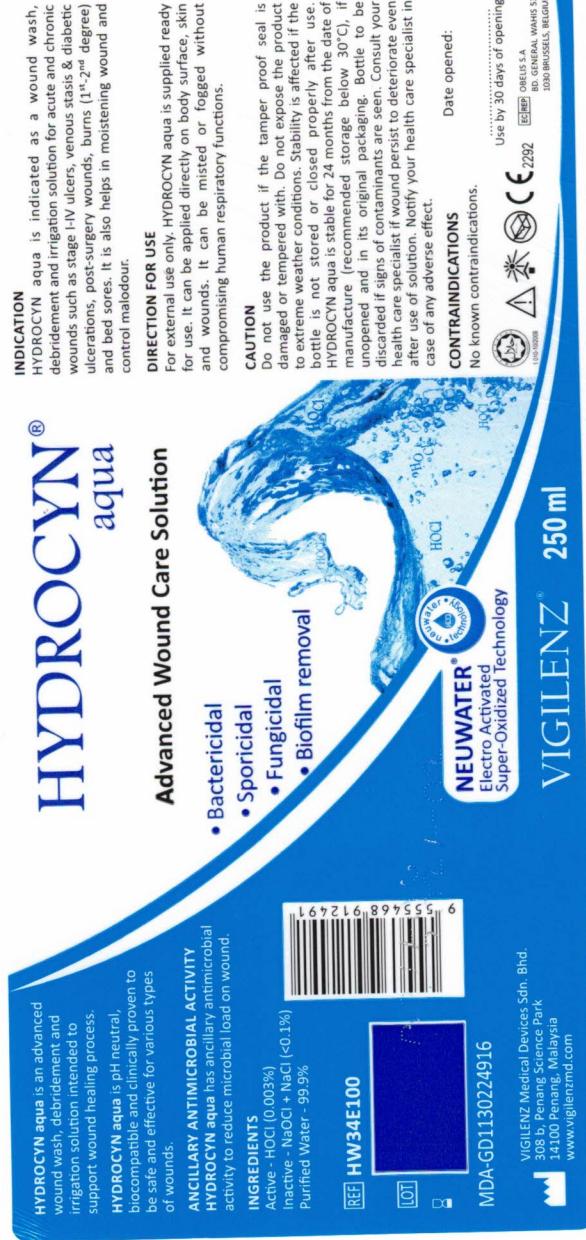
Rework Instruction No. :

R1-PM12-22046

Reference Code	HW34E100	Lot No.	B21406	Lot Quantity (pcs)	4004	Quantity Affected (pcs)	2
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>Bahishir, Dewi</i>						
Required Tools	N/A						
Rework Step	Verified by (PR)	Inspection Details				Verified by (QAQC)	
1) Segregate the affected bottles	<i>Rayana</i> 22/02/22	All the bottles were verified				<i>Daly</i> 22/02/22	
2) Remove the damage labels (Misalignmant printing)	<i>Rayana</i> 22/02/22	All the labels were removed from the bottles				<i>Daly</i> 22/02/22	
3) Replace with new labels	<i>Rayana</i> 22/02/22	New labels were replaced				<i>Daly</i> 22/02/22	
4) Re-print again the Expiry date and Lot number at correct position	<i>Rayana</i> 22/02/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position				<i>Daly</i> 22/02/22	
5) Proceed to Final Control Process	<i>Rayana</i> 22/02/22	Verified in Final Control process and complies with all the specifications				<i>Daly</i> 22/02/22	
<b>Rework Disposition :</b>							
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 : Name : MR.RATNA Date: 22/02/2022	Acknowledge By : Name : MARTINI BINTI GHAZALI Date: 25/2/2022	Approved By : Name : MR.JEEVANEND Date : 25/2/2022					

## REWORK INSTRUCTION

**DESCRIPTION:** Misalignment printing



**VIGILENZ®**

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Aquel, 250 ml (80 Ml cap closure)	Reference No.	HWE100	Date of Inspection	23/12/2020
Lot No.	B1406	Sample Size	250 ml		

*Release Criteria:*

Analysis of Electro Activated Super-Oxidized Water (EASW)					
Result	Instrument	Result	Instrument	Test Disposition (PASS / FAIL)	
				pH Spec: 6.50 - 8.00	ORP (mV) Spec: ≥ 850
7.07	QC-78	861	Q1-67	120	95-140

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : Praj  
Name : Prajwal  
Date : 11/12/2020

Approved By : MARTIN

Name : MARTIN  
Date : 23/02/2020

