

21/2

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY (PCS)	2,004 +12	RS(2) QC(1) +1	ISSUED DATE	15/02/2022
ITEM CODE	H0100001	PACK SIZE	24/Box	+2	LOT NO.	B21564
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD		MFG. DATE	15/02/2022
PREPARED BY	NAME : NUR SHAHIRA <i>Sgt.</i> DATE : 15/02/2022	VERIFIED BY	ODR. NO B099 NAME : RATNASEGARAN <i>N</i> DATE : 15/02/2022		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	IPOC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	9:30 AM 18-02-22 1:00 PM 18-02-22	2016+6 2016+6	NIL	Ky undar 893	Roshni 1:00pm 21/02/22	TANK 500L/T5 03HB180222045 TANK 500L/T1
UDI PRINTING (Label/Box/Carton)				N/A		03HB190222048 UDI NOT REQUIRED FOR THIS LOT
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	10:05 AM 21-02-22 1:00PM 21-02-22	2019+3 2019+3	0	Susi (1025)	Roshni 1:00 pm 21/02/22	- 2 bottle rejected reject replace with new bottle
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	10:05AM 21-02-22 1:00PM 21-02-22	2019+3 2011+3	8	FARAH 1051	Roshni 1:00pm 21/02/22	- 8 label rejected replace with new label
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	10:05 AM 21-02-22 1:00PM 21-02-22	2019+3 2019+3	NIL	FARAH 1051	Roshni 1:00pm 21/02/22	NA
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :				NA		
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :				NA		
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	10:05AM 21-02-22 1:00PM 21-02-22	2019+3 2014+3	NIL	FARAH 1051	Roshni 2:00pm 21/02/22	NA
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	6:00 PM 21-02-22 8:05 PM 21-02-22	84 ctn	84 ctn	NIL	Vister (1023) mang u (846) kyu (891)	Nurin 21/02/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED	2022 btl
QUANTITY FOR QC / RETAIN SAMPLE	4281 btl
SHIPMENT QUANTITY PCS / CTNS	2016 btl / 84 ctns
FINAL SHIPMENT DATE	
COMPLETE/ PARTIAL	COMPLETE PARTIAL

Checked by (PR), Signature : <i>Nel</i> Name: <i>Wynne Satheshan</i> Date: <i>22/2/22</i>	Approved by (QA), Signature : <i>Roshni</i> Name: <i>Rohamza Ohman</i> Date: <i>1/3/2022</i>	Released by (QC), Signature : <i>Edwin</i> Name: <i>MARTINI</i> Designation: <i>QC SUP</i> Date: <i>22/2/22</i> Stamp: <i>1/3/2022</i>
Remarks:		



VIGILENZ®

ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No	QC-LC002
Rev.	00

Item Description	<u>Hydrogen Peroxide, 500ml (Bottle cap closure)</u>
Reference	<u>HU85200</u>
Lot No.	<u>B21S64</u>

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>Jhy</u> 893 21/02/2022	<u>Poly</u> 21/02/22	NP	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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>Jhy</u> 893 21/02/2022	<u>Poly</u> 21/02/22	NP	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"/>	<u>Jhy</u> 21/02/22	<u>Poly</u> 21/02/22	NP	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>Jhy</u> 21/02/22	<u>Poly</u> 21/02/22	NP	Production

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: 1(3)	

Item Description	<i>Hydrogen Aqua, 500ml (Bottle cap closure)</i> <i>Hy55D100 / B11564 2016</i>	
Reference / Lot No.		
Order Qty		
Volume Specification	515	± 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	515 ml	✓	✓	✓	✓	PASS
1/300	515 ml	-	✓	✓	✓	FAIL
1/100	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 ml	-	✓	✓	✓	FAIL
1/300	520 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
1/200	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/200	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL

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	Hydrogen AGW, 500ml (Bottle cap closure)		
Reference / Lot No.	HW35D100 / B1564		
Order Qty	20/6		
Volume Specification	515	±	5 ml

A. Filling Process

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

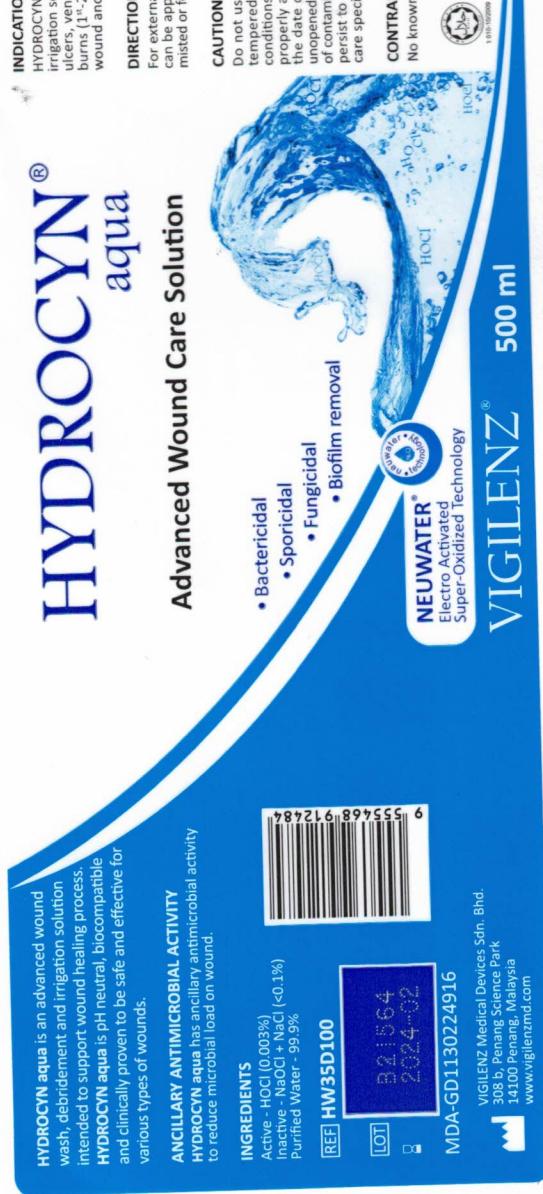
Title: QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		 Bactiguard	Page: 1(3)
Document type: FORM	Doc Id: QC-IP002-09	Issue Date: 15/11/2021	

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

A. Filling Process

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

C. Attachment (First Printed Label)



Doc Id:	Issue Date:	Page:
QC-IP002-09	15/11/2021	2(3)

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 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

OIEHL S.A.
110, 102099
BD. GENERALE, WABIS 5/5
1030 BRUSSELS, BELGIUM
2292

Inspected by : Poly
Name : Puchmi
Date : 3/10/2020

Disposition of the Lot : PASS FAIL

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

D. Attachment (Last Printed Label)



Disposition of the Lot : PASS FAIL

FAIL

Inspected by : Prajitno
Name : Prajitno
Date : 31/10/2021

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

ITEM DESCRIPTION : Hydrogen Aqua, 500mlDoc. No. QC-FC004
Rev. 09REFERENCE : HWS5 D100QTY. PRODUCED (pcs) : 2022LOT NO. : B21569RETAIN SAMPLE QTY. (pes) : Y

No.	Inspection Criteria	Sampling Details	Sample Size	AQL			Results	Status
				Accept	Reject	Accept		
1	Legible and clean printing of label.	50, 0.15	80	0	1	80	0	pass
2	Free from contamination, deformed or damaged on packaging.	50, 0.15	80	0	1	80	0	pass
3	Proper sealing and no leaking.	50, 0.15	80	0	1	80	0	pass
4	Free from contamination / particle / foreign materials on product solution.	50, 0.15	80	0	1	80	0	pass
5	Correct volume filled (against reference sample).	50, 0.15	80	0	1	80	0	pass

Remarks : N/A

Inspected By : Rosy
 Name : Roshni
 Date : 21/2/2022

Approved By : S. S. Murti
 Name : M. M. Murti
 Date : 21/2/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc.
Rev.

DATE :	16/02/2022
REF :	HW35D100
LOT NO. :	B21564

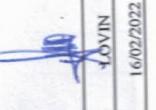
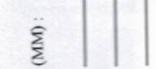
SHOP PACKET QTY (pes) : 2004 +12
 CUSTOMER : VMD (MALAYSIA)
 I.O NO. : 10VMD/11022201

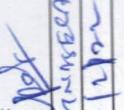
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010220101	pes	2007 +15	2007 +15	2007 +15	2007 +15	✓ Chiaquay
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210901	pes	2007 +15	2007 +15	2007 +15	2007 +15	✓ Chiaquay
3	P0100357	DROPPER STOPPER (500ML & 250ML BOTTLE)		H078220101	pes	2007 +15	2007 +15	2007 +15	2007 +15	✓ Chiaquay
4	N/A	STOCK SOLUTION	N/A	02H13190222098 03H13190222095	ltr	1048	1048	1048	1048	✓ Chiaquay

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)	CONSUMPTION	RECEIVED BY
1	P0100633	LBH-500-RO - Hydrocyn Aqua 500ml Label, Size :71mm X 210mm , Material : White PP + Gloss Lamination		1181211203		2008 +12	✓ Chiaquay			
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)	RECEIVED BY	NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100679	500ml Hydrocyn Aqua carton 469L X 315W X 219H (BAF)		H165211201	84	✓ mohlee						
2	P0100680	500ml nesting short and long-		H065220101	84	✓ mohlee						
3		#N/A										

(4) SPECIAL REQUIREMENT												
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO	SYSTEM CODE	ITEM DESCRIPTION 1	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)			✓ N/A							
2		#N/A										

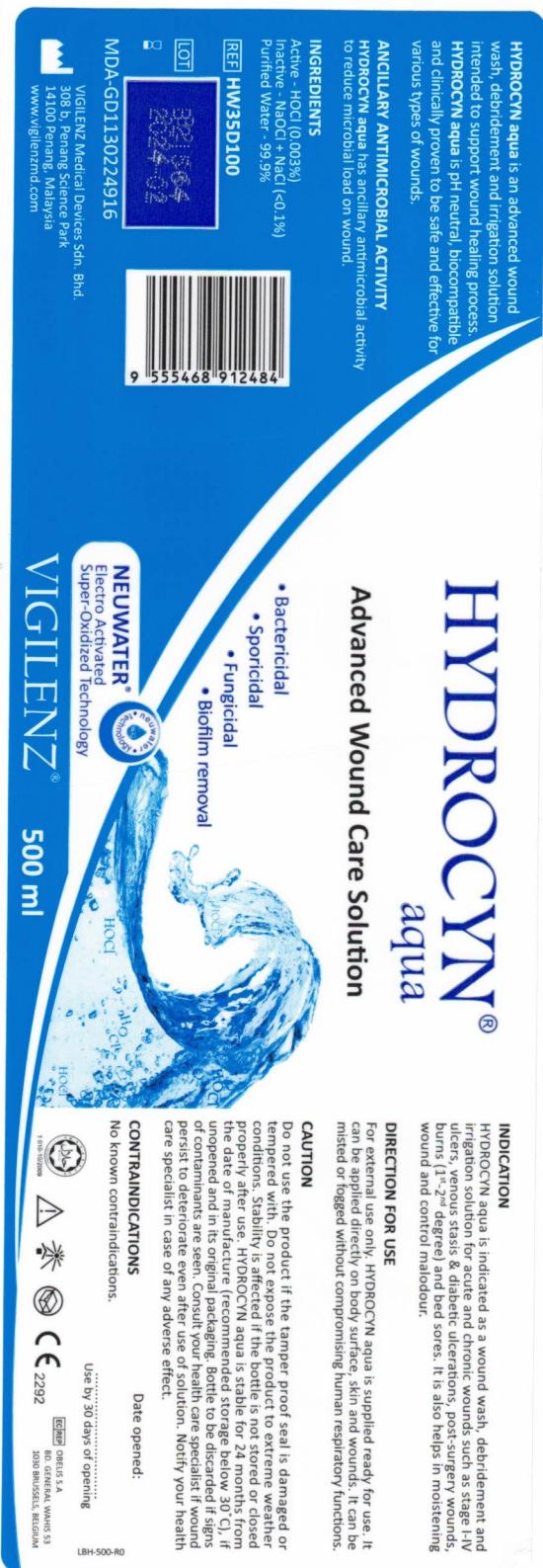
ISSUED BY (MM) : 
 Signature : 
 Name : 
 Date : 16/02/2022

VERIFIED BY (PR) : 
 Signature : 
 Name : 
 Date : 22/1/22

						Rework Instruction No. :	R1-PM12-22044
Reference Code	HW35D100	Lot No.	B21564	Lot Quantity (pcs)	2022	Quantity Affected (pcs)	8
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	Farah						
Required Tools	N/A						
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)		
1) Segregate the affected bottles	✓ Layana 21/02/22	All the bottles were verified			Roly 21/02/22		
2) Remove the damage labels (Misalignmant printing)	✓ Layana 21/02/22	All the labels were removed from the bottles			Roly 21/02/22		
3) Replace with new labels	✓ Layana 21/02/22	New labels were replaced			Roly 21/02/22		
4) Re-print again the Expiry date and Lot number at correct position	✓ Layana 21/02/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			Roly 21/02/22		
5) Proceed to Final Control Process	✓ Layana 21/02/22	Verified in Final Control process and complies with all the specifications			Roly 21/02/22		
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 :	Acknowledge By :	Approved By :					
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI	Name : MR.JEEVANEND					
Date: 21/02/2022	Date: 21/02/22	Date : 21/02/2022					

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



VIGILENZ®

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

VIGILENZ®				Doc No.	QC-PC007
				Rev.	06

Description	Hydrogen bottle	Ag ₂ O cap closure	500 mL	Reference No. HWN35D100	Date of Inspection 21/12/22
Lot No.	B21564		Sample Size (500 mL)		

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
7.24	OC-78	857	OC-67	16	OC-80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 500L / τ₁ 03HB1902202048

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Sander
 Name : Sander moe
 Date : 21/12/22



Approved By : *[Signature]*
 Name : A. R. T. N.I
 Date : 22/12/2022

VIGILENZ®

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

		Doc No.	QC-PC007
		Rev.	06

Description	Hydrogen Peroxide, 500ml (Bottle cap closure)	Reference No.	1035200	Date of Inspection	22/02/2022
Lot No.	B21564	Sample Size	1001 x 500ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)				Test Disposition (PASS / FAIL)	
pH	ORP (mV)	FAC (ppm)			
Spec: 6.50 - 8.00	Spec: > 850	Spec: 95-140			
Result	Instrument	Result	Instrument		
7.33	ORP8	857	ORP 67	1/6	01-00
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 500L / 15 0343/80000045

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rajeshini
Name : Makrini
Date : 03/02/2022

Approved By : Yogini
Name : Kartini
Date : 03/02/2022

