

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY	912	RS: 2 + 1(QC TEST)	ISSUED DATE	07/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX	LOT NO.	A20719	
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	10/01/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 07/01/2022	ODR. NO	A031	EXP. DATE	2024-01	
		VERIFIED BY	NAME : RATNASEGARAN DATE : 07/01/2022		INT. ORDER	IO/VMD/060122/01
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 :	11:50 AM 10-01-22 5:20 PM 10-01-22	915	915	NIL	Wah (893) 10.01.2022	Tank 500L/T5 03HB100122005
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :	11-01-22 11-01-22 12:15 PM 11-01-22					
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	11:05 AM 11-01-22 12:15 PM 11-01-22	915	915	NIL	Wah 12:15 PM 11-01-22	NA
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	11-05 AM 11-01-22 12:15 PM 11-01-22	915	907	8	PARAH (1051) NINIE (1097) 11-01-22	Wah 12:15 PM 11-01-22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	11:05 AM 11-01-22 12:15 PM 11-01-22	915	915	NIL	PARAH (1051) NINIE (1097) 11-01-22	Wah 12:15 PM 11-01-22
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		
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 :	11:05 AM 11-01-22 12:15 PM 11-01-22	915	915	NIL	PARAH (1051) NINIE (1097) 11-01-22	Wah 12:15 PM 11-01-22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	10:30 AM 12-01-22 11:45 AM 12-01-22	38 ctn	38 ctn	NIL	FASLI (1054) HERDI (1053) 12/01/22	NURIN 12/01/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 915 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 2+1 btl
 SHIPMENT QUANTITY PCS / CTNS : 912 btl / 38 ctn
 FINAL SHIPMENT DATE :
 COMPLETE/ PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>Abd</i> Name : RAJASSEGERAN Date : 14/1/22	Approved by (QA), Signature : <i>Jing</i> Name : Rohamza Shahrin Date : 21/1/2022	Released by (QC), Signature : <i>Martini</i> Name : MARTINI Designation : QC DEPT Date : 14/01/2022 Stamp : <i>14/01/2022</i>
Remarks: 13/1/2022		
		

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

Doc. No	QC-LC002
Rev.	00

Item Description	Hydrocyn Aqua, 500ml (Bottle cap closure)		
Reference	HW35 D 100		
Lot No.	A20719		

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 893</u> 11/01/2022	wah 1037 11.01. 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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>wah 823</u> 11/01/2022	wah 1037 11. 01. 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"/>	<u>wah</u> 11/1/22	wah 11.01. 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"/>	<u>wah</u> 11/1/22	wah 11.01. 22	N A	Production

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	

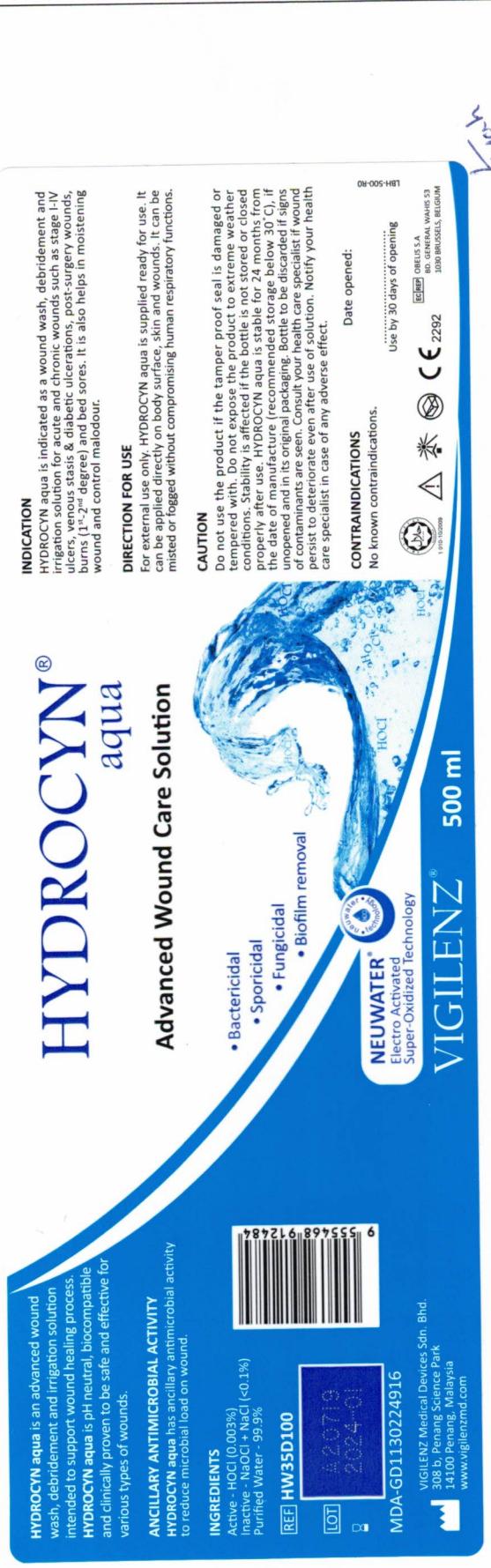
Item Description	Hydrocyn Aqua, 500 ml (Bottle cap closure)		
Reference / Lot No.	HW35D100 / A20719		
Order Qty	q12		
Volume Specification	≥ 515	± 5	ml

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

C. Attachment (First Printed Label)



Inspected by : Lazir
 Name : Wahidah
 Date : 10.01.2022

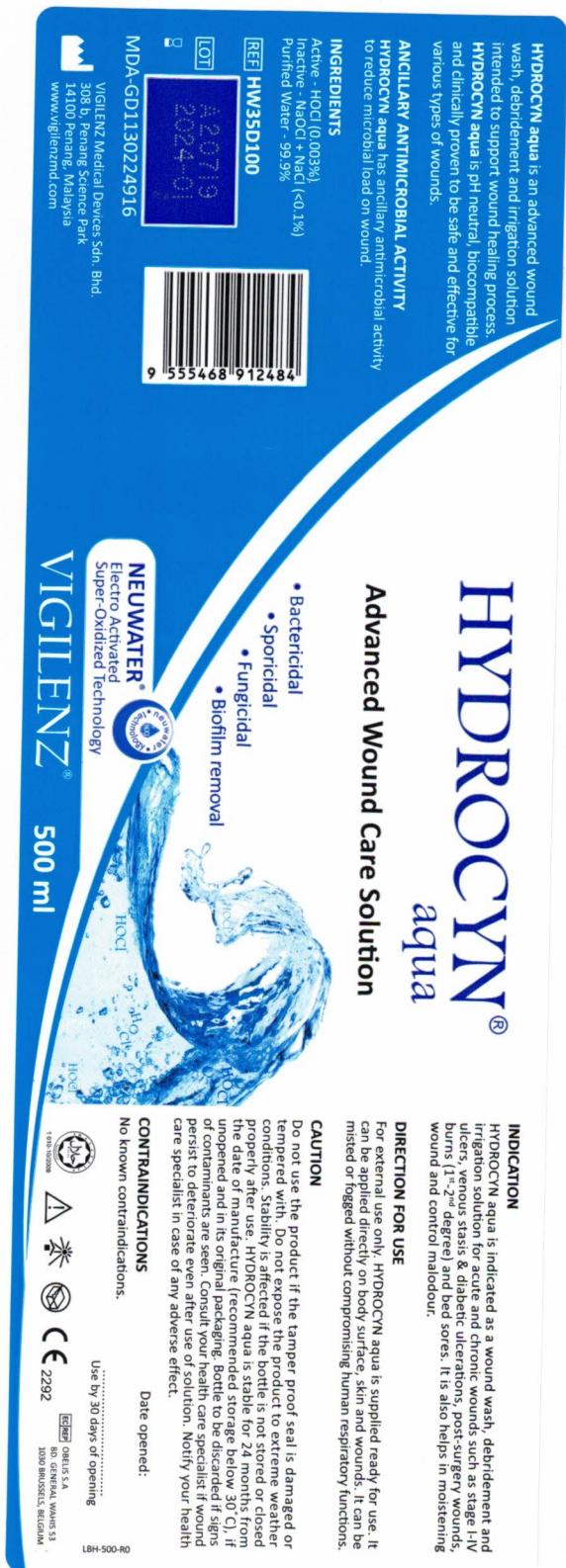
Disposition of the Lot : PASS FAIL

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
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D. Attachment (Last Printed Label)

Disposition of the Lot :

PASS FAIL

Inspected by : Wook
Name : Wook Wook
Date : 11.01.2022

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		Doc. No. Rev.	QC-FC004 09
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ITEM DESCRIPTION : Hydrogen Aqua, 500 mL

REFERENCE : HW 35D100

LOT NO. : A20719

QTY. PRODUCED (pcs) :
RETAIN SAMPLE QTY. (pcs) :

915
2

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

Remarks : N/A

Approved By : M. Martin
Name : M. Martin
Date : 11/01/2022

Inspected By : Lynch
Name : Lynch
Date : 11/01/2022

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RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE :	11/01/2022
REF :	HW3SD100
LOT NO. :	A20719

SHOP PACKET QTY (pes) : 912 RS :
 CUSTOMER : VMD (MALAYSIA)
 I.O NO. : IO/VMD/060122/01

		RECEIVED BY
		<i>Layana</i>

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2		LOT NO.	QTY REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
			UOM	UOM					
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)		H010211101	pes	915		<i>Layana</i>
2	P0100200	Blue Cap for 500ml HDPE Plastic Container	0		H020210601	pes	915		<i>Layana</i>
3	P0100357	DROPPER STOPPER (500ML & 250ML BOTTLE)			H078211101	pes	915		<i>Layana</i>
4	N/A	STOCK SOLUTION	N/A		03H81D01022005	ltr	475		<i>Layana</i>

(2) PRODUCT PACKAGING

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	ITEM DESCRIPTION 1			RECEIVED BY	
						NO.	SYSTEM CODE	ITEM DESCRIPTION 1		
1	P0100633	LBH-500-R0 - Hydrocyan Aqua 500ml Label, Size : 71mm X 210mm, Material : White PP + Gloss Lamination	L18211102	916	<i>Layana</i>	1	P0100679	500ml Hydrocyan Aqua carton -469L X 315W X 219H (BAF)	H165211103	38 <i>Melvish</i>
2		#N/A				2	P0100680	500ml nesting short and long-	H065211103	38 <i>Melvish</i>
3		#N/A				3		#N/A		
4		#N/A								
5		#N/A								
6		#N/A								
7		#N/A								

(4) SPECIAL REQUIREMENT

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)			<i>N/A</i>
2					#N/A

ISSUED BY (MM):

LOVIN
 Signature :
 Name :
 Date : 11/01/2022

VERIFIED BY (PR):

Karen
 Signature :
 Name :
 Date : 11/01/2022

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Aqueous 500ml (Bottle Cap Closure)	Reference No.	HU35D/00	Date of Inspection	2/11/2022
		Lot No.	A20719	Sample Size	1btl X 500l

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH	ORP (mV)	ORP (mV)	FAC (ppm)	Test Disposition (PASS / FAIL)	
Spec:	Spec: > 850	Spec: > 850	Spec: 95 - 140		
Result	Instrument	Result	Instrument	Result	Instrument
7.52	Q1-78	860	Q1-67	112	Q1-80
					pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/A*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Rajesh*
Name : *Rajesh*
Date : *12/01/22*

Approved By : *Martini*
Name : *Martini*
Date : *12/01/2022*



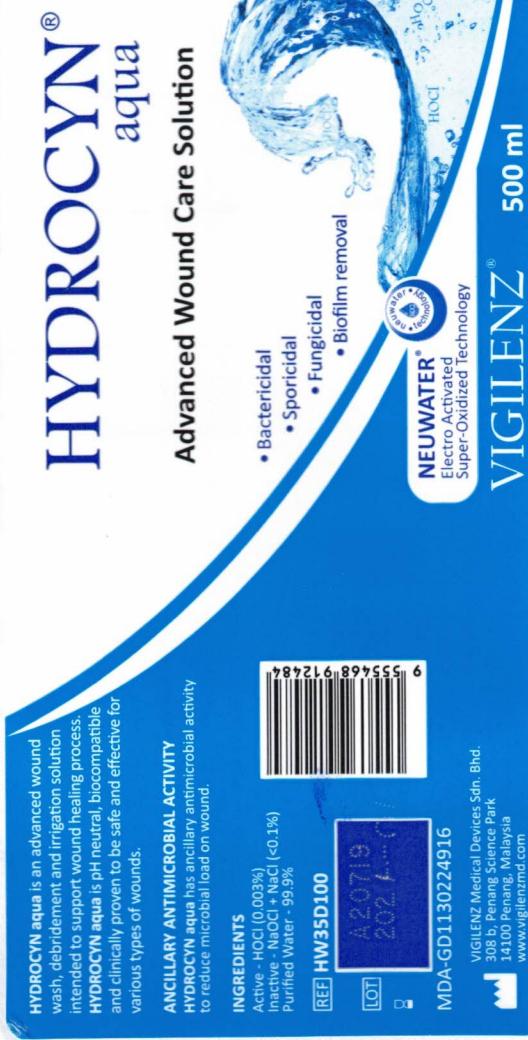
Rework Disposition :

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: 11/01/2022	Date: 11/01/2022	Date : 11/01/2022

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



HYDROCYN aqua is an advanced wound wash, debridement and irrigation solution intended to support wound healing processes. **HYDROCYN aqua** is pH neutral, biocompatible and clinically proven to be safe and effective for various types of wounds.

ANCILLARY ANTIMICROBIAL ACTIVITY
HYDROCYN aqua has ancillary antimicrobial activity to reduce microbial load on wound.

INGREDIENTS
Active - HOCl (0.003%)
Inactive - NaOCl + NaCl (<0.1%)
Purified Water - 99.9%

REF HW25D100
LOT A20739202

MDA.GD1130224916

INDICATION
HYDROCYN aqua is indicated as a wound wash, debridement and irrigation solution for acute and chronic wounds such as staged 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 persists to deteriorate even after use of solution. Notify your health care specialist in case of any adverse effect.

CONTRAINDICATIONS

No known contraindications.

LBH-500-RD

Use by 30 days of opening
ORLIS S.A.
BD. GENERAL WATHS 53
1030 BRUSSELS, BELGIUM
1/10/10/2008
CE 2292