

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY	912	RS: 2 + 1(QC TEST)	ISSUED DATE	07/01/2022
ITEM CODE	H010001	PACK SIZE	24/BOX	LOT NO.	A21100	
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)	MFG. DATE	10/01/2022	
PREPARED BY	NAME : NUR SHAHIRA <i>[Signature]</i> DATE : 07/01/2022	VERIFIED BY	NAME : RATNASEGARAN <i>[Signature]</i> DATE : 07/01/2022	EXP. DATE	2024-01	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton	N/A	INT. ORDER	10/VMD/060122/01	
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 :	1:50 PM 10-01-22	915	915	Nil	Kyandren	wah 10.01.22 03HB100122006
UDI PRINTING (Label/Box/Carton)						UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	10:30 PM 11-01-22	915	915	Nil	NINIE	Roshni 1:45 pm NA
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	12:30 PM 11-01-22	915	908	7	FARAH (1051)	Roshni 1:45 pm 11/01/22 - 7 Label reject replace w/ new label
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	12:30 PM 11-01-22	915	915	Nil	FARAH (1051)	Roshni 1:45 pm NA
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :						
BOX PACKING & PRINTING (Applicable for 100ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	12:30 PM 11-01-22	915	915	Nil	FARAH (1051)	Roshni 2:05 pm 11/1/22 NA
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	4:00 PM 12-01-22	38 ctn	38 ctn	Nil	FASLI (1059) HERDI (1053)	NURIN 12/01/2022 12/01/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :						UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 915 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 3 BH
 SHIPMENT QUANTITY PCS / CTNS : 912 btl / 38 ctns
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>[Signature]</i> Name : RATNASEGARAN Date : 07/01/2022	Approved by (QA), Signature : <i>[Signature]</i> Name : RONALDA BINTI MARTINI Date : 07/01/2022	Released by (QC), Signature : <i>[Signature]</i> Name : MARTINI Designation : QC DEPT Date : 14/01/2022 Stamp : 
Remarks:		

VIGILENZ®

ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No	QC-LC002
Rev.	00

Item Description	Hydrocyn Aqua, 500mL (Bottle cap closure)
Reference	HWW 35 D 100
Lot No.	A 21100

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"/>	Kya han 893	Wah 1037	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"/>	Kyanden 893	Wah 1037	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"/>	Wah 11/122			Technician
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"/>	Wah 11/122			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:
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Item Description	Hydrocyn Aqua, 500ml (Bottle cap closure)	
Reference / Lot No.	HW35D100 912	
Order Qty	515 ± 5 ml	
Volume Specification		

A. Filling Process

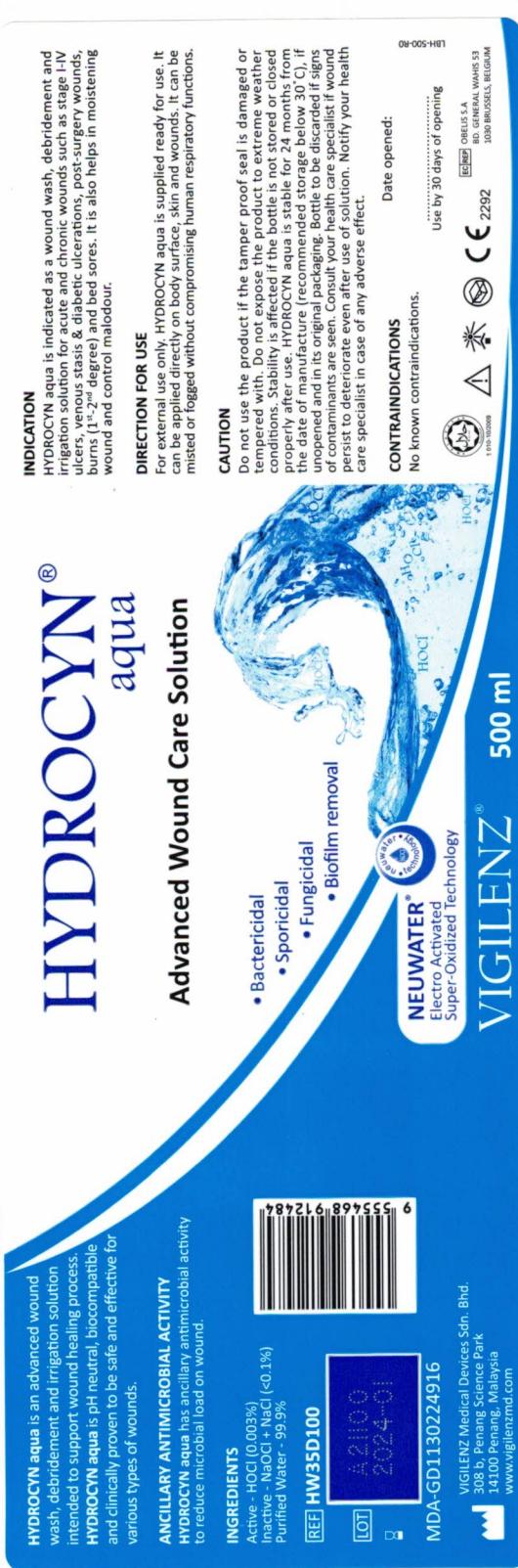
Sampling / Frequency	Volume Inspected (ml)	No contamination of foreign material / dirt	Functionality of Sprayer or Dispenser (applicable to bottle only)	Proper Cap Sealing/Stopper	No Leaking Observed		Test Disposition	
					PASS	FAIL	PASS	FAIL
10/10	520 mL	✓	✓	✓	✓	✗	✗	□
1/300	520 mL	✓	✓	✓	✓	✗	✗	□
1/300	520 mL	✓	✓	✓	✓	✗	✗	□
1/305	520 mL	✓	✓	✓	✓	✗	✗	□
					NP		□	□
							□	□

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	
					PASS	FAIL
10/10	✓	✓	✓	✓	✗	✗
1/300	✓	✓	✓	✓	□	□
1/300	✓	✓	✓	✓	□	□
1/305	✓	✓	✓	✓	□	□
	NP				□	□
					□	□

Title: 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: 2(3)

C. Attachment (First Printed Label)



Name : web web
Date : 11.01.22
Inspected by : locan

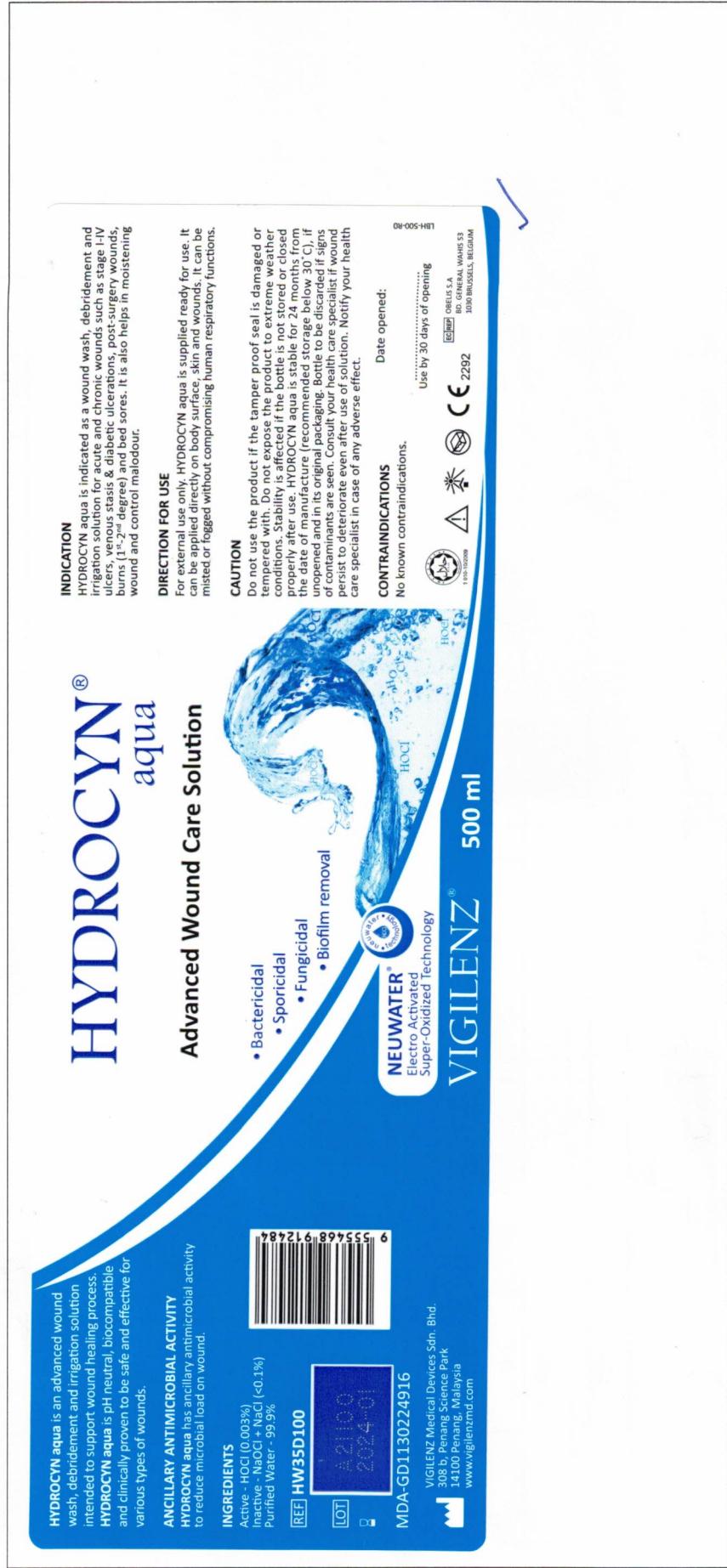
FAIL

PASS

Disposition of the Lot:

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

D. Attachment (Last Printed Label)



Disposition of the Lot : PASS FAIL

Inspected by : Rozay
Name : Rozhani
Date : 11/11/2022

VIGILENZ®	FINAL CONTROL TEST REPORT -		
	ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
	Doc. No.	QC-FC004	
	Rev.	09	

ITEM DESCRIPTION : Hypogen Arrow, 500ml
 REFERENCE : HWD35D100
 LOT NO. : A21100

QTY. PRODUCED (pcs) : 915
 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.	<u>S3, 0.1S</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>0</u>	<u>pass</u>
2	Free from contamination, deformed or damaged on packaging.	<u>S3, 0.1S</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>0</u>	<u>pass</u>
3	Proper sealing and no leaking.	<u>S3, 0.1S</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>0</u>	<u>pass</u>
4	Free from contamination / particle / foreign materials on product solution.	<u>S3, 0.1S</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>0</u>	<u>pass</u>
5	Correct volume filled (against reference sample).	<u>S3, 0.1S</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>	<u>0</u>	<u>pass</u>

Remarks : N/D

Approved By : Rajeshwari
 Name : KARPATI
 Date : 11/01/2022

Inspected By : Rajeshwari
 Name : KARPATI
 Date : 11/01/2022

VIGILENZ *

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.:
Rev.

DATE :	11/01/2022
REF :	HW3SD100
LOT NO. :	A21100

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

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)	(w/ Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H01021101	pes	915		915	915	✓ <i>Angga</i>
2	P0100200	Blue Cap for 500ml HDPE Plastic Container		0			H020210601	pes	915	✓ <i>Angga</i>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H07821101	pes	915		915	915	✓ <i>Angga</i>
4	N/A	STOCK SOLUTION		N/A	ltr	475		475	475	✓ <i>Angga</i>
				Q3HB100122016						

(3) OVER WRAPPING AND CARTON PACK										
NO	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	QTY RECEIVED (pes)	LOT NO.	QTY REQUIRED (pes)	QTY RECEIVED (pes)	RECEIVED BY
1	P0100633	LBH-500-RG - Hydrocyan Aqua 500ml Label , Size : 71mm X 210mm , Material : White PP + Gloss Lamination		L18J211102	916	✓ <i>Angga</i>	P0100679	500ml Hydrocyan Aqua carton - 469L X 315W X 219H (BAF)	H165211103	38 ✓ <i>Melati</i>
2		#N/A					P0100680	500ml nesting short and long-	H065211103	38 ✓ <i>Melati</i>
3		#N/A						#N/A		
4		#N/A								

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

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

ISSUED BY (MM) :

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

VERIFIED BY (PR) :

RATNASEKARAN
Signature : _____
Name : RATNASEKARAN
Date : 14/1/2022

VIGILENZ®

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

		Doc No.	QC-PC007
Rev.		Date	06

Description	Hydrogen Peroxide (Bottle Cap Closure)	Reference No.	HW852100	Date of Inspection	12/01/2022
Lot No.		Sample Size	100ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH Spec: 6.50 - 8.00	ORP (mV) Spec: > 850	FAC (ppm) Spec: 95 - 140	Test Disposition (PASS / FAIL)		
Result	Instrument	Result	Instrument	Result	Instrument
7.51	Q1-78	868	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 : *Rony*
Name : *Roshni*
Date : *12/01/22*

Approved By : *Praveen*

Name : *MARTIN*
Date : *12/01/2022*



HYDROCYN aqua is an advanced wound wash, debridement and irrigation solution intended to support wound healing process.

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 (0.03%)
Inactive - NaOCl + NaCl (<0.1%)
Purified Water - 99.9%

REF HW35D100

LOT A211000



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

HYDROCYN® aqua

Advanced Wound Care Solution

- Bactericidal
- Sporicidal
- Fungicidal
- Biofilm removal



CONTRAINDICATIONS

No known contraindications.

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.

Date opened:

Use by 30 days of opening

LBH-500-R0



1010-00000

Δ ☀ ☇

CE

2292

ICP Belgium

OB. GÉNÉRAL MANS 53

1000 BRUXELLES, BELGIUM



500 ml

