

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY (PCS)	2,064	RS: 2+1 (QC TEST)	ISSUED DATE	27/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX	4+2 cf 27/01/22	LOT NO.	A22711
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	27/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 27/01/2022	VERIFIED BY	ODR. NO A159		EXP. DATE	2024-01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	NAME : RATNASEGARAN DATE : 27/01/2022			INT. ORDER	IO/VMD/130122/01
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 :	8:00pm 24-01-22	2067+3	2067+3	N/i	Kyandam 893	Wah 1037 25.1.22
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	11:00am 28-01-22 3:30 pm 28-01-22	2067+3	2067+3	N/i	Laxmi	Roshini 3:20 pm 28/01/22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	11:00am 28-01-22 3:30 PM 28-01-22	2067+3	2065+3	2	Kyu (887)	Roshini 3:20 pm 28/01/22
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	11:00am 28-01-22 3:30 PM 28-01-22	2067+3	2067+3	N/i	Kyu (887)	Roshini 3:20 PM 28/01/22
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 :				N/A		
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 :	11:00am 28-01-22 3:30 PM 28-01-22	2067+3	2067+3	N/i	Kyu (887)	Roshini 3:20 pm 28/01/2022
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	3:10PM 28-01-22 3:30pm 29-01-22	86 ctn	86 ctn	N/i	HERO1 (1053) NETRA	Jinda 29/01/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED : 2067+3 2070615

QUANTITY FOR QC / RETAIN SAMPLE : 400+261

SHIPMENT QUANTITY PCS / CTNS : 2064 4Lts 186 ctns

FINAL SHIPMENT DATE : 27/01/2022

COMPLETE/PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <u>Nur Shahira</u> Name : <u>Ramya Sankaran</u> Date : <u>27/01/2022</u>	Approved by (QA), Signature : <u>dmz</u> Name : <u>Dronamiza Ghani</u> Date : <u>4/2/2022</u>	Released by (QC), Signature : <u>3. Janix</u> Name : <u>MARTINI</u> Designation : <u>QC DEPT</u> Date : <u>3/2/2022</u> Stamp :
Remarks: SAMPLE REQUEST BY CUSTOMER PRIZMA TRADE SERBIA		

RELEASED
QUALITY CONTROL

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

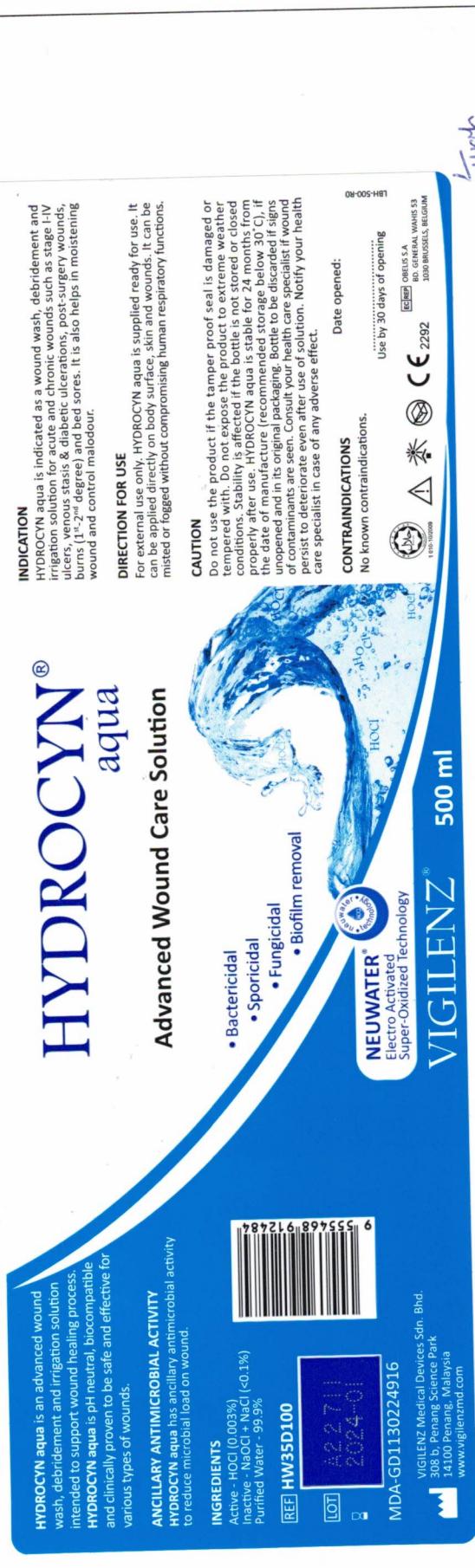
Item Description	Hydrocyn Aqua, 500 ml (Bottle cap closure)		
Reference / Lot No.	HW35D00 / A22711		
Order Qty	2064		
Volume Specification	515	±	5 ml

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
Document type: FORM	Issue Date: 15/11/2021

C. Attachment (First Printed Label)



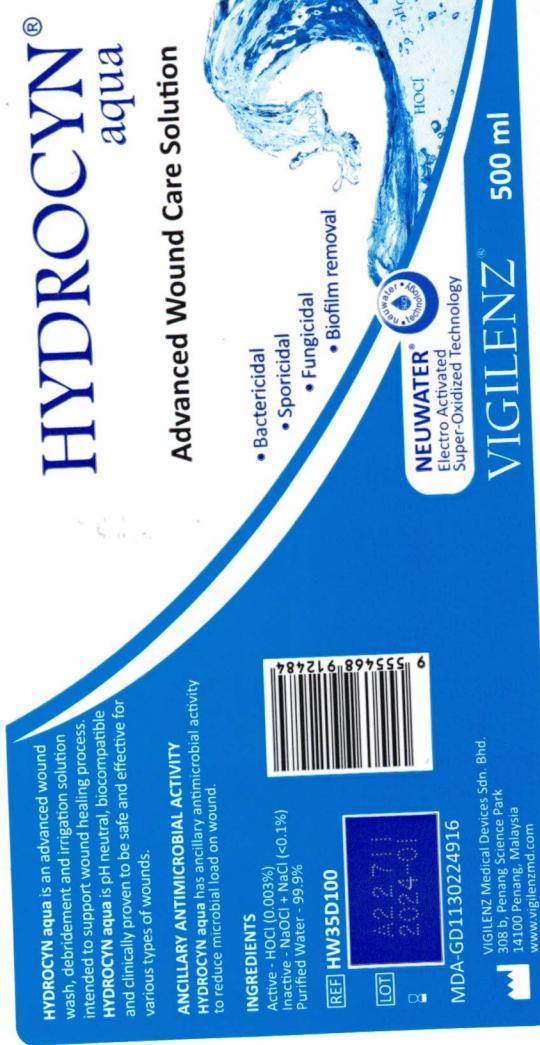
Inspected by : Wah
 Name : Wah Wah
 Date : 28.01.2022

FAIL

PASS

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

D. Attachment (Last 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 (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 (recommend 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 persists 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
18H-505-94
OEHLS SA
BD. GENERAL WAHIS 53
1030 BRUSSELS, BELGIUM

Inspected by : Rajesh
Name : Rajesh
Date : 28/11/2021

FAIL

PASS

Disposition of the Lot :

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

REFERENCE : H035.D100

QTY. PRODUCED (pcs) :

2070

LOT NO. :

A2011

RETAIN SAMPLE QTY. (pcs) :

212

No.	Inspection Criteria	Sampling Details	Sample Size	AQL		Results	Status
				Accept	Reject		
1	Legible and clean printing of label.	<u>S3, 0/15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>
2	Free from contamination, deformed or damaged on packaging.	<u>S3, 0/15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>
3	Proper sealing and no leaking.	<u>S3, 0/15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>
4	Free from contamination / particle / foreign materials on product solution.	<u>S3, 0/15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>
5	Correct volume filled (against reference sample).	<u>S3, 0/15</u>	<u>80</u>	<u>0</u>	<u>1</u>	<u>80</u>	<u>0</u>

Remarks :

N/A

Inspected By : Rajy
Name : Pogni
Date : 28/01/2022

Approved By : Martini
Name : Martini
Date : 28/01/2022

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

DATE :	28/01/2022
REF :	HW3SD100
LOT NO. :	A22711

SHOP PACKET QTY (pes) : 2064
 CUSTOMER : VMD (MALAYSIA)
 LO NO. : IO/VMD/130122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H01021101	pes	2067 +3	2067 +3	2067 +9	1. <u>Zanjaya</u>
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210601	pes	2067 +3	2067 +3	2067 +3	1. <u>Zanjaya</u>
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H07821101	pes	2067 +3	2067 +3	2067 +3	1. <u>Zanjaya</u>
4	N/A	STOCK SOLUTION	N/A	03H02340102017 03H02340102020	ltr	1078	1078	1078	1. <u>Zanjaya</u>

(2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100633	LBH-500-R0 - Hydrocyan Aqua 500ml Label , Size : 71mm X 210mm , Material : White PP + Gloss Lamination	L18211201	2068 +3	<u>Kanjaya</u>
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.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100679	500ml Hydrocyan Aqua carton -4691 X 315W X 219H (BAF)	HK65211103	86	<u>Medief</u>
2	P0100680	500ml nesting short and long-	HK65211103	86	<u>Medief</u>
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)	N/A	N/A	
2		#N/A			

ISSUED BY (MM) : Not
 Signature : LOVIN
 Name : LOVIN
 Date : 28/01/2022

VERIFIED BY (PR) : Not
 Signature : LOVIN
 Name : LOVIN
 Date : 29/1/22

VIGILENZ®

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

		Doc No.	QC-PC007
		Rev.	06

Description	Hydrogen Aqui, 500ml (Both cap closure)	Reference No.	HN095 D100	Date of Inspection	29/01/2022
Lot No.	A02711	Sample Size	1btl x 500ml		

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: >850	Spec: 95-110	Instrument	Result	Instrument
7.16	Q1.78	865	Q1.67	110	Q1-80 Pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 500L/T5 01H0340122017

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Ray
Name : Roshni
Date : 29/01/2022

Approved By : M. Martin
Name : M. Martin
Date : 3/2/2022



VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide 500ml (Bottle Cap closed)	Reference No.	H1185.D100	Date of Inspection	29/01/2023
Lot No.	112211	Sample Size	1001 x 500ml		

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: ≥ 850	Spec: 95-140		
Result	Instrument	Result	Instrument	Result	Instrument
7.24	Q1C-78	852	Q1C-67	114	Q1C-80
					PASS

RO water and product bioburden meeting the acceptance criteria.

Remarks : Tank 1000L/T7 024402070122020

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : Rajesh
Name : MARTIN
Date : 29/01/2023

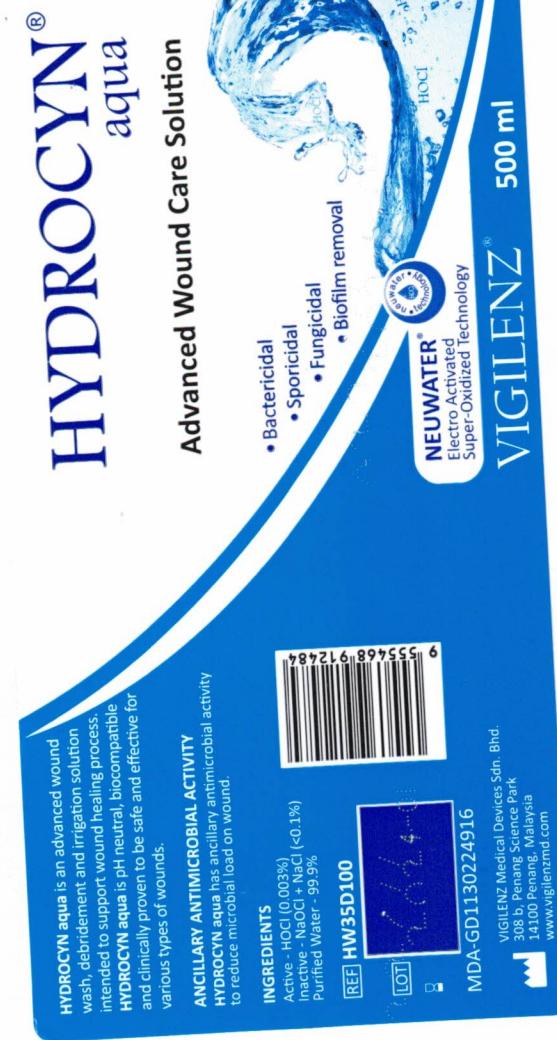
Approved By : E. J. Martin
Name : MARTIN
Date : 29/01/2023



Rework Instruction No. : R1-PM12-22029-72032						
Reference Code	HW35D100	Lot No.	A22711	Lot Quantity (pcs)	2070	Quantity Affected (pcs)
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	<i>Mkyu</i>					
Required Tools	N/A					
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)	
1) Segregate the affected bottles	<i>Carina</i> 28/01/22	All the bottles were verified			<i>Lily</i> 28/1/22	
2) Remove the damage labels (Misalignment printing)	<i>Carina</i> 28/01/22	All the labels were removed from the bottles			<i>Lily</i> 28/1/22	
3) Replace with new labels	<i>Carina</i> 28/01/22	New labels were replaced			<i>Lily</i> 28/1/22	
4) Re-print again the Expiry date and Lot number at correct position	<i>Carina</i> 28/01/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Lily</i> 28/1/22	
5) Proceed to Final control Process	<i>Carina</i> 28/01/22	Verified in Final control process and complies with all the specifications			<i>Lily</i> 28/1/22	
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 : <i>MR.RATNA</i>	Acknowledge By : <i>MARTINI BINTI GHAZALI</i>			Approved By : <i>MR.JEEVANEND</i>		
Name : MR.RATNA	Name : MARTINI BINTI GHAZALI			Name : MR.JEEVANEND		
Date: 28/01/2022	Date: 28/01/2022			Date : 28/01/2022		

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



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.

Advanced Wound Care Solution

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 (0.003%)

Inactive - NaCl (<0.1%)

Purified Water - 99.9%

REF HW35D100

[LOT]



MDA-GD1130224916
VIGILENZ Medical Devices Sdn. Bhd.
30815, Penang Science Park
14100 Penang, Malaysia
www.vigilenzmd.com

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.

LBH-500-PA
Use by 30 days of opening
ORLUS S.A.
100 GENERAL WAHIS 53
1030 BRUSSELS BELGIUM
1910-02008

Date opened:

