

## SHOP PACKET - EASW

REFERENCE	HW36D100	ODR. QTY	480	RS: 2 + 1 (QC TEST)	ISSUED DATE	02/03/2022
ITEM CODE	H0100007	PACK SIZE	12/BXS	LOT NO.	A22712	
ITEM DESCRIPTION	Hydrocyn Aqua, 1000ml (Bottle Cap Closure)	CUSTOMER	PROJECTMED TOMASZ SUROWIEC	MFG. DATE	02/03/2022	
PREPARED BY	NAME : NUR SHAHIRA <i>8F</i> DATE : 02/03/2022	ODR. NO	A160	EXP. DATE	28/02/2024	
		VERIFIED BY		NAME : RATNASEGARAN DATE : 02/03/2022	INT. ORDER	IO/PRO/004582/01
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	0733330201223	UDI-DI NO. (2nd Packaging) - Carton	1733330201220			
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)0733330201223 (17)28022024	(11)02032022 (10)A22712	UDI-PI NO. (2nd Packaging) - Carton	(01)1733330201220 (17)28022024	(11)02032022 (10)A22712	

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	7:40 PM 10-03-22	483	483	NIL	Roshni (893) 11/03/2022	Pushni 8:15 AM 11/03/2022 Tank 300L/TB 03H8100822075
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :	6:30 PM 11-03-22	483	483	5	Nisya 980	Roshni 7:20 PM 11/03/2022
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	11:04 PM 12-03-22	483	483	NIL	SOPIA (1138)	Roshni 6:25 PM 12/03/22
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	7:05 PM 12-03-22	483	480	3	Lina (1131)	Roshni 12/03/2022
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	7:05 PM 12-03-22	483	483	NIL	Lina (1131)	Roshni 8:40 PM 12/03/2022
CAP SEALING (Applicable for 1000mL )						
TIME START : DATE : TIME COMPLETE : DATE :						
BOX PACKING & PRINTING (Applicable for 1000ml only)						
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 1000 mL & Bags only)						
TIME START : DATE : TIME COMPLETE : DATE :						
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	7:30 PM 12-03-22	483	483	NIL	Lina (1131)	Roshni 8:40 PM 12/03/2022
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	8:00 PM 14-03-22	40 ctn	40 ctn	NIL	FARI 1054 HEROI 1053	Junior 14/03/2022
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	8:00 PM 14-03-22	40 ctn	40 ctn	NIL	FARI 1054	Junior 14/03/2022

QUANTITY PRODUCED	483 btl
QUANTITY FOR QC / RETAIN SAMPLE	21 btl
SHIPMENT QUANTITY PCS / CTNS	480 btl
FINAL SHIPMENT DATE	
COMPLETE / PARTIAL	COMPLETE

Checked by (PR), Signature : <i>Not</i>	Approved by (QA), Signature : <i>fmz</i>	Released by (QC), Signature : <i>E. Rajesh</i>
Name : RATNASEGARAN Date : 15/3/22	Name : Rohanisa Othman Date : 22/3/2022	Name : <i>MAZINI</i> Designation : IPQC SUPERVISOR Date : 15/3/2022 Stamp :
Remarks:		
		

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

Doc. No	QC-LC002
Rev.	00

Item Description	Hydrogen Peroxide, 1000ml (Bottle cap closure)
Reference	H/W 362/00
Lot No.	A22712

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>Abdul</u> 873 12/03/2022	<u>Poly</u> 12/03/2022	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 checked="" type="checkbox"/>	<u>Abdul</u> 873 12/03/2022	<u>Poly</u> 12/03/2022	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>Surajna</u> 12/03/22	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>Surajna</u> 12/03/22	NP	Production

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

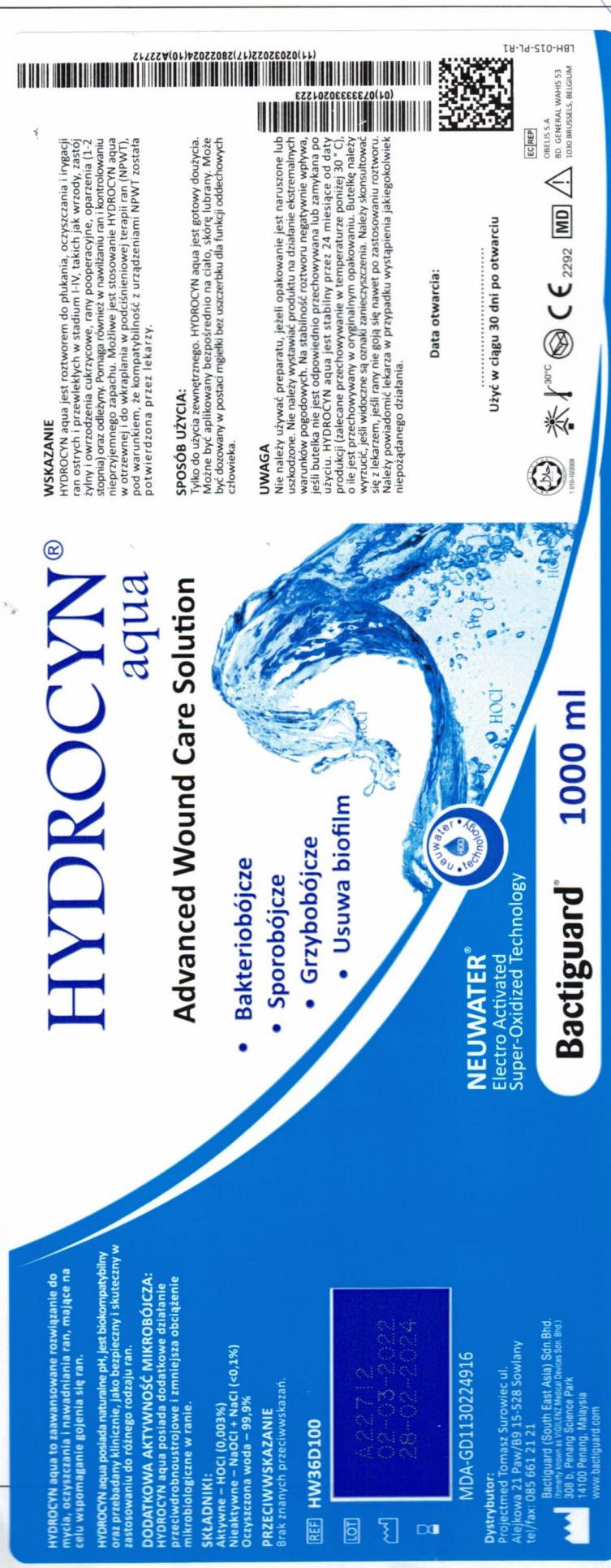
Item Description	<u>Hydrocyn Dosey, 1000 ml (B01H cop closure)</u>
Reference / Lot No.	<u>HWS62100 / A2712</u>
Order Qty	<u>480</u>
Volume Specification	<u>1020 ± 20 ml</u>

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

**C. Attachment (First Printed Label)**



**Disposition of the Lot :**  PASS  FAIL

**Inspected by :** *Raj Pashul*  
**Name :** \_\_\_\_\_  
**Date :** *14/08/2023*

Title:	QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	
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FORM  
QC-IP002-09

D. Attachment (Last Printed Label)



Bactiguard
Issue Date:
15/11/2021

Page:  
3(3)

Inspected by : Piotr Pochmajer  
Name : Pochmajer  
Date : 14/08/2021

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

		Doc. No.	QC-FC004
		Rev.	09

ITEM DESCRIPTION :

Hydrogen Aquor, 1000 ml

REFERENCE :

HW 860/00

LOT NO. :

A01712

QTY. PRODUCED (pes) :

483

RETAIN SAMPLE QTY. (pes) :

2

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

Remarks :

N/P

Inspected By :

Rajiv  
Roshni

Name

M.A.R.T.M  
15/03/2022

Approved By :

Rajiv

Name

M.A.R.T.M  
15/03/2022

Date

## RAW MATERIAL LOADING FORM (RMLF)

Doc. No.  
Rev.

DATE :	03/02/2022
REF :	HW36D100
LOT NO. :	A22712

SHOP PACKET QTY (pcs) : 480  
 CUSTOMER : PROJECTMED TOMASZ SUROWIEC (POLAND)  
 I.O.NO. : IOPRO/004582/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	CONSUMPTION	RECEIVED BY
									1 Czajna
1	P0100799	1000ml HDPE Plastic Container		0	pc	483	483	483	483
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container		0	pc	483	483	483	483
3	P0100357	DROPPER, STOPPER	(500ML & 250ML BOTTLE)	H078210701	pc	483	483	483	483
4		STOCK SOLUTION			lt	498	498	498	498

## (2) PRODUCT PACKAGING

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100537	LBH-015-PL-R0 - Hydrocyon 1000ml Label (Polish), Size: 250mm x 110mm, Material: White PP + Gloss	L18F220301	484	1 Czajna
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 (pcs)	RECEIVED BY
1	P0100582	DSN-H-011(A) - VIG-001-CTN Printed Carton for Hydrocyon 1000ml,Size: 380 x 290 x 220mm(E), Mat: T180/MT/T180 BA FLUTE	H103220201	40	mech
2	P0100583	DSN-H-011(B) - VIG-904-ASY,NL: 377 x 145mm (2/pos) & NS: 282 x 145mm(3/pos) for Carton E , Mat: T150/T150 B Flute	H041210501	40	mech
3	P0100584	DSN-H-011(C) - VIG-904-ASY, Layer Pad for Carton E, Size: 377 x 282mm, Mat: T150/T150 B Flute	H042200201	40	mech

## (4) SPECIAL REQUIREMENT

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

ISSUED BY (MM) :

Signature :

Name :

Date :

VERIFIED BY (PR) :   
 Signature :   
 Name : Manager  
 Date : 03/02/2022

Title: OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD

Document type:  
FORM

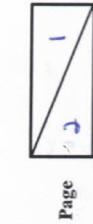
<b>SHIPMENT</b>	<input type="checkbox"/>	<b>TOTAL LOTS</b> : <u>1</u>	<b>RETURN DATE</b> : <u>N/A</u>	<b>Bactiguard</b>
<b>GAMMA</b>	<input type="checkbox"/>	<b>TOTAL CARTONS</b> : <u>40</u>	(Applicable for Gamma only)	
		<b>SAMPLING DETAILS</b> : <u>1, WRL 1.5</u>	<b>AVAILABILITY OF RETAIN SAMPLES</b> :	<b>YES / NO</b>
Doc ID:	QC-OI001-04	Issue Date:	09/02/2022	Page: 1(2)

**TOTAL LOTS** : 1  
**TOTAL CARTONS** : 40  
**SAMPLING DETAILS** : 1, WRL 1.5

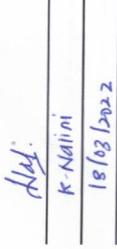
DATE	PRODUCT TYPE	REF. NO.	LOT NO.	QTY (BKS / PCS / BTLS) / CARTON	CARTON NO.	INSPECTION CRITERIA			REMARKS	
						PRODUCT NOT TEAR / DAMAGE	CARTON NOT DAMGE / DENT	QUANTITY CARTON CHECKED	QUANTITY CARTON CHECKED / CARTON	
14/02/2022	Hydroquin Eye	Hydroquin Eye	1400100	100	100	✓	✓	✓	✓	Shop Package should Correspond to Ref No. & Lot No. Date, Expiry Date & Lot No. Product Code, Manufacturing Number (UDI Number).

\*Please print addition sheet if required

Inspected by : J. Jaiswal  
Name : J. Jaiswal  
Date : 14/02/2022



Verified by  
Name : K. Nalin  
Date : 18/03/2022



Title:

OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD

Document type:  
FORM

Doc ID:	Bactiguard
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A. Attachment (Carton UDI label)

## Bactiguard®

PRODUCT : Hydrocyn Aqua, 1000ml
QUANTITY : 12 PCS

Manufacturer:

Bactiguard (South East Asia) Sdn Bhd  
(formerly known as VIGILENZ Medical Devices Sdn Bhd)  
308b, Jalan Perindustrian Bukit Minyak 18,  
Penang Science Park, 14100 Penang, Malaysia.



REF HW36D100

LOT A22712

EX 28-02-2024



(01)173333020122011020320221728022024(10)A22712

\*Only print this sheet for products with UDI

Inspected by : Jinnyk  
Name : 14/09/2022  
Date :



Verified by : K. Nalin  
Name : 18/03/2022  
Date :

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide, 1000 ml (bottle cap closure)	Reference No.	HWSL D100	Date of Inspection	14/03/2019
Lot No.	12211	Sample Size	1 bottle x 1000 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: ≥ 850	Spec: 95 - 140	Result	Instrument	Instrument
7.22	858	91-67	118	Q1-80	pass

RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot :  RELEASE  ON-HOLD

Analyzed By : Woh  
 Name : Woh woh  
 Date : 14-3-2022

Approved By : J. Rajan  
 Name : Mr. Rajan  
 Date : 15/3/2022



VIGILENZ®	REWORK INSTRUCTION	Doc. No	PR-RI001
		Rev	04

#### **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 :  OB	Acknowledge By : 	Approved By : 
Name : MUHD. ARIFUDDIN	Name : MARTINI BINTI GHAZALI	Name : NURUL BALKIS ZAMRI
Date: 12/03/2022	Date: 15/3/2022	Date : 16/3/2022

