

SHOP PACKET - EASW

REFERENCE	HW35D100	ODR. QTY	2,016	RS: 2 + 1 (QC TEST)	ISSUED DATE	27/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX	LOT NO.	A22714	
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	PROJECTMED TOMASZ SUROWIEC	MFG. DATE	27/01/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 27/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 27/01/2022	EXP. DATE	28/12/2023	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	07333330201124	UDI-DI NO. (2nd Packaging) - Carton	17333330201121	INT. ORDER	IO/PRO/004582/01	
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)07333330201124 (17)28122023	(11)27012022 (10)A22714	(01)17333330201121 (17)28122023	(11)27012022 (10)A22714		

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION				N/A		
TIME START : DATE : TIME COMPLETE : DATE :						
UDI PRINTING (Label/Box/Carton)	2020	2020	NIL	Nirya 980	Roshni 4:20 PM 10/03/2022	NA
TIME START : DATE : TIME COMPLETE : DATE :	11:30 AM 10-03-22 4:20 PM 10-03-22					
SOLUTION FILLING & CAPPING				N/A		
TIME START : DATE : TIME COMPLETE : DATE :						
LABELLING	2019 2020 PA 10/03/22	2006 10/03/22	14	A11D (1143)	Roshni 10:50 AM 11/03/2022	-14 pcs reject replace with new label NA 10/03/22
TIME START : DATE : TIME COMPLETE : DATE :	6:00 PM 10-03-22 10:50 AM 10-03-22					
PRINTING LOT NUMBER	2020 2019 PA 10/03/22	2020 2019 PA 10/03/22	NIL	E19 (932)	Roshni 10:50 AM 11/03/22	NA
TIME START : DATE : TIME COMPLETE : DATE :	6:00 PM 10-03-22 10:50 AM 10-03-22					
CAP SEALING (Applicable for 1000mL)				N/A		
TIME START : DATE : TIME COMPLETE : DATE :						
BOX PACKING & PRINTING (Applicable for 1000ml only)			N/A			
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 1000 mL & Bags only)			N/A			
TIME START : DATE : TIME COMPLETE : DATE :						
FINAL CONTROL	2019 2020 PA 10/03/22	2019 2020 PA 10/03/22	NIL	E19 (932)	Roshni 11/03/2022 11:00 AM	ND
TIME START : DATE : TIME COMPLETE : DATE :	6:00 PM 10-03-22 10:50 AM 10-03-22					
CARTON PACK	4:00 PM 10-03-22 12:00 PM 10-03-22	84 ctn	84 ctn	NIL	Heraf (1053)	Nurin 12/3/2022
TIME START : DATE : TIME COMPLETE : DATE :						
UDI LABELLING	4:00 PM 10-03-22 12:00 PM 10-03-22	84 ctn	84 ctn	NIL	Madiham (912)	Nurin 12/3/2022
TIME START : DATE : TIME COMPLETE : DATE :						

QUANTITY PRODUCED :	2019 446
QUANTITY FOR QC / RETAIN SAMPLE :	RS 261
SHIPMENT QUANTITY PCS / CTNS :	2016 446 / 84 ctn
FINAL SHIPMENT DATE :	
COMPLETE/PARTIAL :	COMPLETE PARTIAL

Checked by (PR), Signature : <i>Abt</i>	Approved by (QA), Signature : <i>JMB</i>	Released by (QC), Signature : <i>SAKTHI</i>
Name : Rizwah Arsham Date : 14/3/22	Name : Rohanisa Ghuman Date : 22/3/2022	Name : IPQC SUPERVISOR Designation : IPQC SUPERVISOR Date : 14/3/2022
Remarks:		
		

SHOP PACKET - EASW						
CODE	HW35D100	ODR. QTY (PCS)	2,016	RS: 2 + 1 (QC TEST)	ISSUED DATE	27/01/2022
CODE	H0100001	PACK SIZE	24/BOX	LOT NO.	A22714	
DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	PROJECTMED TOMASZ SUROWIEC (POLAND)		MFG. DATE	27/01/2022
PREPARED BY	NAME : NUR SHAHIRA DATE : 27/01/2022	VERIFIED BY	ODR. NO. A162	EXP. DATE	2024-01	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	N/A	UDI-DI NO. (2nd Packaging) - Carton	NAME : RATNASEGARAN DATE : 27/01/2022			
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 :	7:00pm 27-01-22	2013+6	2019	Nil	Kynden 873	Wah 8:15AM 28/01/2022
TIME COMPLETE : DATE :	8:15AM 28-01-22					Tank 1000L/TG 03HB270122021
UDI PRINTING (Label/Box/Carton)						UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE :						
TIME COMPLETE : DATE :						
SOLUTION FILLING & CAPPING						
TIME START : DATE :	3:45 PM 28-01-22	2019	2018	1	VIKI (1094)	Pashni 10:15AM 29/01/22
TIME COMPLETE : DATE :	10:15 AM 29-01-22					- Blue cap rejects replace with new cap
LABELLING						
TIME START : DATE :	3:45PM 28-01-22	2019	2017	0	SARAH (1102) (FARAH (1051))	Pashni 10:15AM 29/01/22
TIME COMPLETE : DATE :	10:15 AM 29-01-22					- 2 label reject replace with new label
PRINTING LOT NUMBER						
TIME START : DATE :	3:45PM 28-01-22	2019	2019	NIL	SARAH (1102) FARAH (1051)	Pashni 10:15AM 29/01/22
TIME COMPLETE : DATE :	10:15 AM 29-01-22					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 :						
FINAL CONTROL						
TIME START : DATE :	3:45PM 28-01-22	2019	2019	NIL	SARAH (1012) FARAH (1051)	Pashni 10:30AM 29/01/22
TIME COMPLETE : DATE :	10:15 AM 29-01-22					NA
CARTON PACK						
TIME START : DATE :	1:00 PM 29-01-22	84	84	Nil	FARI (1053) HERDI (1054) RAHIM (1088)	Jinds 29/01/22 29/01/2022
TIME COMPLETE : DATE :	3:30 PM 29-01-22	ctn	ctn			
UDI LABELLING						
TIME START : DATE :						
TIME COMPLETE : DATE :						

QUANTITY PRODUCED : 2016 btl
 QUANTITY FOR QC / RETAIN SAMPLE : 2157 btl
 SHIPMENT QUANTITY PCS / CTNS : 2013 btl / 84ctns
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature :	Approved by (QA), Signature :	Released by (QC), Signature :
Name : RATNASEGARAN Date : 29/1/22	Name : Rohama Osman Date : 8/2/2022	Name : MARTINI Designation : QC DEPT Date : 3/2/2022 Stamp :
Remarks: SAMPLE REQUEST BY CUSTOMER PRIZMA TRADE SERBIA		
 Doc. No.: PB-SP907, Rev. 01		

VIGILENZ®

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

VIGILENZ®		CHECKLIST FOR LINE CLEARANCE OF ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)	
Item Description		Doc. No	QC-LC002
Reference		Rev.	00
Lot No.	A 22714		
Hydrogen Aqua, 500ml (bottle cap closure)			
H.W 350100			

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"/>	Kyandam 28/01/22	Wah 28.01.22	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"/>				
	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 28/01/22	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"/>		Wah 28/01/22	N A	Production

Title:

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Document type:
FORMDoc Id:
QC-IP002-09Issue Date:
15/11/2021Page:
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			 Bactiguard
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Item Description	<i>Hydrocyn Aqua, 500ml (Bottle cap closure)</i>
Reference / Lot No.	<i>HW35D100 A22714</i>
Order Qty	<i>2016</i>
Volume Specification	<i>515 ± 5 ml</i>

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	500 mL	↙	↙	↙	↙	FAIL
1/300	500 mL	↖	↙	↙	↙	PASS
1/300	500 mL	↖	↙	↙	↙	PASS
1/300	500 mL	↖	↙	↙	↙	PASS
1/300	500 mL	↖	↙	↙	↙	PASS
1/300	500 mL	↖	↙	↙	↙	PASS
1/300	500 mL	↖	↙	↙	↙	PASS
1/300	500 mL	↖	↙	↙	↙	PASS

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	↖	↖	↖	↖	FAIL
1/300	↖	↖	↖	↖	PASS
1/300	↖	↖	↖	↖	PASS
1/300	↖	↖	↖	↖	PASS
1/300	↖	↖	↖	↖	PASS
1/300	↖	↖	↖	↖	PASS
1/300	↖	↖	↖	↖	PASS

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

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Item Description	Hydrocyn Blue, 500 ml (80% cap closure)		
Reference / Lot No.	HW852001/022714		
Order Qty	20/6		
Volume Specification	5/5	±	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
1/20q	520ml	✓	✓	✓	✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	FAIL
					✓	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
1/20q	✓	✓	✓	✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL
				✓	FAIL

Title:

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Document type:
FORMPage:
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QC-IP002-09**C. Attachment (First Printed Label)**

HYDROCYN aqua to zaawansowane rozwijanie do mycia, oczyszczania i nawadniania ran, mające na celu wspomaganie gojenia się ran.

HYDROCYN aqua posiada naturalne pH, jest biokompatybilny oraz przebadany klinicznie jako bezpieczny i skuteczny w zastosowaniu do różnego rodzaju ran.

DODATKOWA AKTYwnośĆ MIKROBÓICZNA: HYDROCYN aqua posiada dodatkowe działanie przeciwdrobnoustrojowe i zmniejsza obciążenie mikrobiologiczne w ranie.

SKŁADNIKI:

Aktywne – HOCl (0,003%)
Niezakwaszone – NaOCl + NaCl (<0,1%)
Oczyszczona woda – 99,9%

REF: HW35D100

MDA-GD1130224916
122714
2024-01
OT

Distributor:
Projectmed Thomas Saruwatari,
Alleykova 21, Pav 89/15-538 Sowilany,
14100 Penang, Malaysia.
tel/fax: 085 361 2121
Vigilenz Medical Devices Sdn. Bhd.
308 b Penang Science Park,
14100 Penang, Malaysia.
www.vigilenzmd.com

HYDROCYN®

aqua

Advanced Wound Care Solution

- Bakteriobójcze
- Sporobójcze
- Grzybobójcze
- Usuwa biofilm

NEUWATER®
Electro Activated
Super-Oxidized Technology

VIGILENZ® 500 ml



WSKAZANIE
HYDROCYN aqua jest roztworem do płukania, oczyszczania i mycia ran ostrych i przewlekłych w stadium I-IV, takich jak wrzody, zastój żyły i owrzodzenia cukrzycowe, rany pooperacyjne, oparzenia (1-2 stopnia) oraz odieżowy. Pomaga również w nawilżaniu ran i kontrolowaniu nieprzyjemnego zapachu.

SPOSÓB UŻYCIA:
Tylko do użycia zewnętrznego. HYDROCYN aqua jest gotowy do użycia. Może być aplikowany bezpośrednio na ciało, skórę lub ranę. Może być dozowany w postaci mgiełki bez uszczerebku dla funkcji oddychowej czworaka.

UWAGA:
Nie należy używać preparatu, jeżeli opakowanie jest naruszone lub uszkodzone. Nie należy wystawiać produktu na działanie ekstremalnych warunków pogodowych. Na stabilność roztworu negatywnie wpływa, jeśli butelka nie jest odpowiednio przechowywana lub zamknięta po użyciu. HYDROCYN aqua jest stabilny przez 24 miesiące od daty produkcji (założane przechowywanie w temperaturze poniżej 30 °C), jeśli nie jest przechowywany w oryginalnym opakowaniu. Butelkę należy wytrącić, jeśli widać na niej znaki zanieczyszczenia. Należy skonsultować się z lekarzem, jeśli rany nie goją się nawet po zastosowaniu roztworu. Należy powiadomić lekarza w przypadku wystąpienia jakiegokolwiek niepożądanej działania.

PRZECIWWSKAZANIE
Brak znanych przeciwwskazań.
Data otwarcia: 18.09.2028
Użyć w ciągu 30 dni po otwarciu
Użyć w ciągu 30 dni po otwarciu
CE 2292
ORIELS S.A.
BD GENERAL WAIMS 53
1030 BRUSSELS, BELGIUM

Disposition of the Lot : PASS FAIL

FAIL

Inspected by : Wojciech
Name : Wojciech
Date : 28.01.22

Title:

QC IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

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D. Attachment (Last Printed Label)

Disposition of the Lot : PASS FAIL

PASS FAIL

Inspected by : Rajy
 Name : Rajy
 Date : 29/11/2021

VIGILENZ®

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

ITEM DESCRIPTION : Hydrogen Peroxide 500 mL

REFERENCE : HW35D100

LOT NO. : A22714

Doc. No.	QC-FC004
Rev.	09

QTY. PRODUCED (pcs) : 2019

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.	SG, 0.15	80	0	1	80	0	0	pass
2	Free from contamination, deformed or damaged on packaging.	SG, 0.15	80	0	1	80	0	0	pass
3	Proper sealing and no leaking.	SG, 0.15	80	0	1	80	0	0	pass
4	Free from contamination / particle / foreign materials on product solution.	SG, 0.15	80	0	1	80	0	0	pass
5	Correct volume filled (against reference sample).	SG, 0.15	80	0	1	80	0	0	pass

Remarks : NP

Inspected By : Robby
Name : Roshni
Date : 29/01/2022

Approved By : Eduardo
Name : KARTINI
Date : 3/2/2022

DATE :	28/01/2022
REF :	HW3SD100
LOT NO. :	A22714

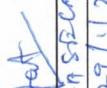
SHOP PACKET QTY (pes) : 2016
 CUSTOMER : PROJECTMED TOMASZ SUROWIEC (POLAND)
 LO. NO. : 10/PRO/004582/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	# CONSUMPTION		RECEIVED BY
								# CONSUMPTION	# CONSUMPTION	
1	P0100242	500ml HDPE Plastic Container (New Version)	(c/w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010210201	pcs	2019*	2019	2019	2019	✓ Czajka
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210301	pcs	2019	2019	2019	2019	✓ Czajka
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210101	pcs	2019	2019	2019	2019	✓ Czajka
4		STOCK SOLUTION	03H1B270100021	ltr	1050	1050	1050	1050	1050	✓ Czajka

(2) PRODUCT PACKAGING						(3) OVER WRAPPING AND CARTONPACK					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
1	P0100506	LBH-001-PL-R0 MCC - Hydrocyan 500ml Polish Label, Size: 210mm X 71mm (Roll Form), White PP + Gloss Lamination (6 colors)	L18C200501	2020	✓ Czajka	1	P0100679	500ml Hydrocyan Aqua carton -469L X 315W X 219H (BAF)	H165211103	84	✓ Czajka
2		#N/A				2	P0100680	500ml nesting short and long-	H065211103	84	✓ Czajka
3		#N/A				3		#N/A			

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

ISSUED BY (MM) : 
 Signature : LOVIN
 Name :
 Date : 28/01/2022

VERIFIED BY (PR) : 
 Signature : PARIS STOJANOW
 Name :
 Date : 29/1/22

VIGILENZ®

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

Doc No. QC-PC001
Rev. 06

Description	Hydrogen Peroxide, 500mL (Bottled Cap Change)	Reference No.	Hu0350100	Date of Inspection	29/01/2022
Lot No.	A02714	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:	Spec: > 850	Spec: 95 - 140	Result	Instrument	Instrument
7.01	866	00-80	114	00-67	PASS

RO water and product bioburden meeting the acceptance criteria.

Remarks : *NP*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Raj*
Name : *POSTMAN*
Date : *29/01/2022*

Approved By : *Engr. S. M. V. I.*
Name : *M. V. I.*
Date : *3/2/2022*



Rework Instruction No. :

RI-PM12-22030

033 fmz
7/2/2022

Reference Code	HW35D100	Lot No.	A22714	Lot Quantity (pcs)	2019	Quantity Affected (pcs)	1+1					
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	Rajana 29/01/22	All the bottles were verified			Praj 29/1/22							
2) Remove the damage labels (Misalignmant printing)	Rajana 29/01/22	All the labels were removed from the bottles			Praj 29/1/22							
3) Replace with new labels	Rajana 29/01/22	New labels were replaced			Praj 29/1/22							
4) Re-print again the Expiry date and Lot number at correct position	Rajana 29/01/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			Praj 29/1/22							
5) Proceed to Final control Process	Rajana 29/01/22	Verified in Final control process and complies with all the specifications			Praj 29/1/22							
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 :

Name : MR.RATNA

Date: 29/01/2022

Acknowledge By :

Name : MARTINI BINTI GHAZALI

Date: 3/2/2022

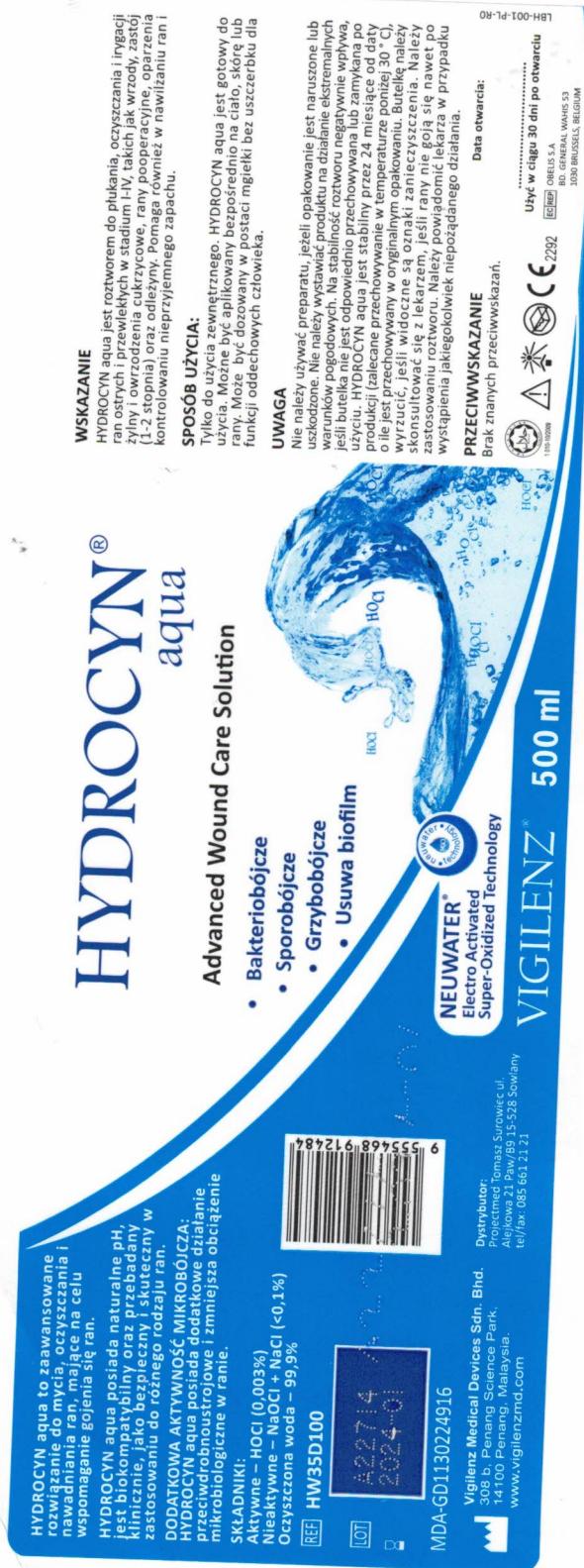
Approved By :

Name : MR.JEEVANEND

Date : 3/2/2022

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



Title:	OUTGOING QUALITY CONTROL (OQC) INSPECTION RECORD	
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A. Attachment (Carton UDI label)

Bactiguard®

PRODUCT : Hydrocyn Aqua, 500ml
QUANTITY : 24 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 HW35D100

LOT A22714

EXPIRY 28-12-2023



(01)1733330201121(11)27012022(17)28122023(10)A22714

*Only print this sheet for products with UDI

Inspected by : Nurin
 Name : Nurin
 Date : 11/3/2023

Page 1 of 2

Verified by : _____
 Name : _____
 Date : _____

K-Audi

1/63/2023



ASTROLOGIC QUALITY CONTROL (000C) INSPECTION RECORD

GOING GLOBAL (cont'd.)

Document type:
FORM

Issue Date: 09/02/2022 Page: 1(2)

Doc ID:
OC-00001-04

SHIPMENT	<input checked="" type="checkbox"/>	TOTAL LOTS : <u>1</u>
GAMMA	<input type="checkbox"/>	TOTAL CARTONS : <u>84</u>
		SAMPLING DETAILS : <u>I, AQL 1.5</u>

RETURN DATE

(Applicable for Gamma only)

YES / NO

(Applicable for Gamma only)

SAMPLES

**Please print addition sheet if required*

Inspected by

Inspected by _____
Name _____

Page

Verified by
Name

B
Balances
11/03/2023

						Rework Instruction No. :	R1-PM12-22054
Reference Code	HW35D100	Lot No.	A22714	Lot Quantity (pes)	2019	Quantity Affected (pes)	2019
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	Change label Poland (Old design) to new design with UDI						
Potential Adverse Effect (Filled by QA)	Scratch marks on bottles						
Training / Trainer (Tick whichever applicable)	<input type="checkbox"/>	Required	<input type="checkbox"/> / <input type="checkbox"/>	Not Required	Trainer : N/A		
Rework Operator	<i>Favah, Era, elin</i>						
Required Tools	N/A						
Rework Step		Verified by (PR)	Inspection Details			Verified by (QAQC)	
1) Segregate all the bottles		<i>Tanjong</i> 10/03/22	All the boxes were verified			<i>Rozly</i> 10/03/22	
2) Remove all labels from the bottles		<i>Tanjong</i> 10/03/22	All the labels were removed from the bottles			<i>Rozly</i> 10/03/22	
3) Replace with new labels with UDI		<i>Tanjong</i> 10/03/22	New labels with UDI were replaced			<i>Rozly</i> 10/03/22	
4) Re-print again the Expiry date and Lot number at correct position		<i>Tanjong</i> 10/03/22	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Rozly</i> 10/03/22	
5) Proceed to Final Control Process		<i>Tanjong</i> 10/03/22	Verified in Final Control process and complies with all the specification			<i>Rozly</i> 10/03/22	
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>Muhd Arif</i>	Acknowledge By : <i>Era</i>		Approved By : <i>Zamri</i>				
Name : MUHD. ARIFUDDIN	Name : MARTINI BINTI GHAZALI		Name : NURUL BALKIS ZAMRI				
Date: 10/03/2022	Date: <i>10/03/2022</i>		Date : <i>10/03/2022</i>				

REWORK INSTRUCTION

DESCRIPTION: Change Label

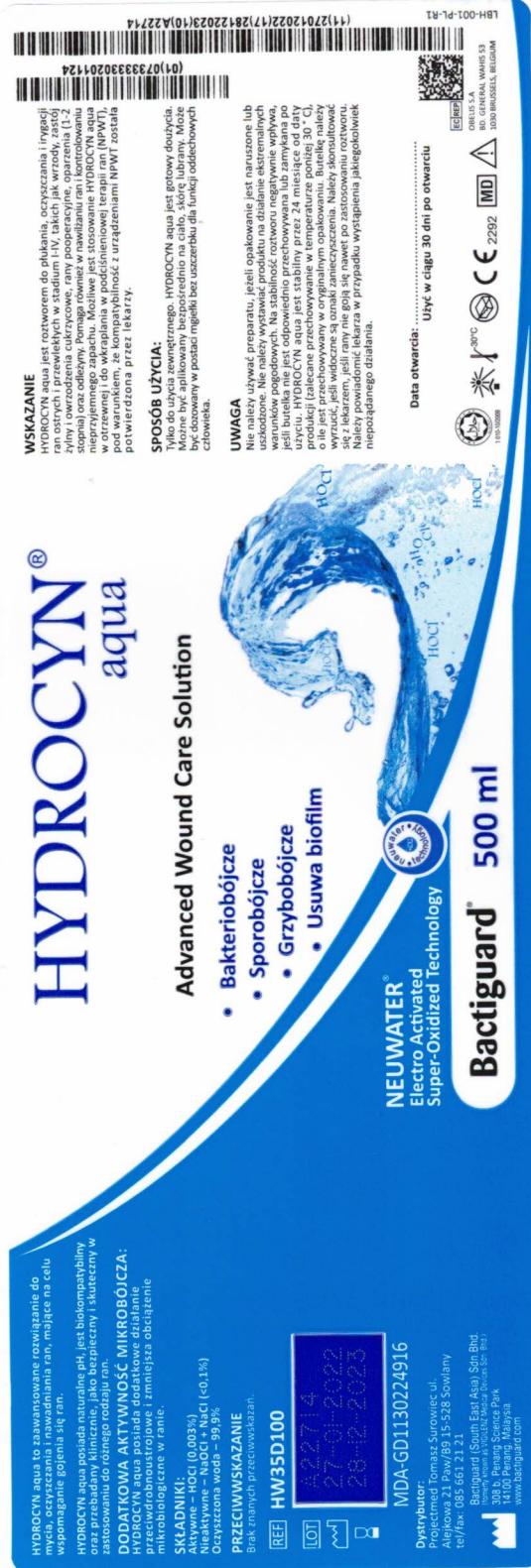
BEFORE



REWORK INSTRUCTION

DESCRIPTION: Change Label

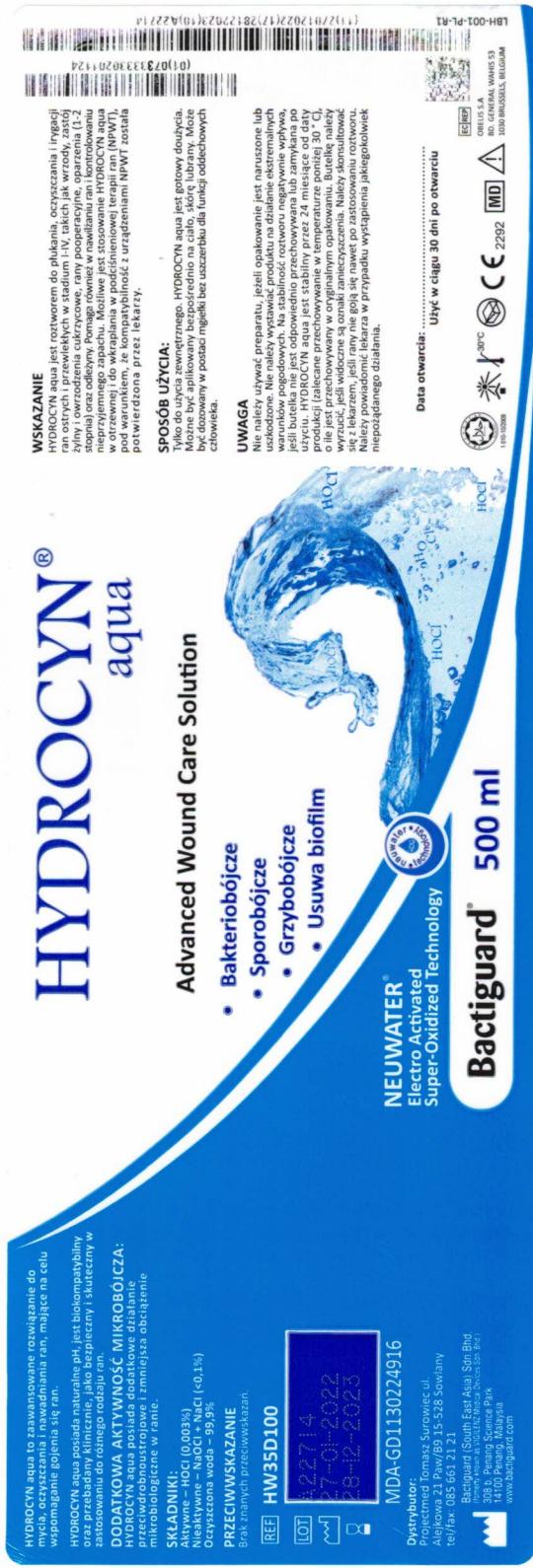
AFTER



Rework Instruction No. : R1-PM12-22056						
Reference Code	HW35D100	Lot No.	A22714	Lot Quantity (pcs)	2019	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 type="checkbox"/> / <input type="checkbox"/>	Not Required	Trainer : N/A	
Rework Operator	<i>Era, farah, Sofia</i>					
Required Tools	N/A					
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)	
1) Segregate the affected bottles	<i>1 Guyana 11/03/22</i>	All the bottles were verified			<i>Poly 11/03/2022</i>	
2) Remove the damage labels (Misalignmant printing)	<i>1 Guyana 11/03/22</i>	All the labels were removed from the bottles			<i>Poly 11/03/2022</i>	
3) Replace with new labels	<i>1 Guyana 11/03/22</i>	New labels were replaced			<i>Poly 11/03/22</i>	
4) Re-print again the Expiry date and Lot number at correct position	<i>1 Guyana 11/03/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Poly 11/03/22</i>	
5) Proceed to Final Control Process	<i>1 Guyana 11/03/22</i>	Verified in Final Control process and complies with all the specifications			<i>Poly 11/03/22</i>	
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>[Signature]</i>	Acknowledge By : <i>[Signature]</i>			Approved By : <i>[Signature]</i>		
Name : MUHD. ARIFUDDIN	Name : MARTINI BINTI GHAZALI			Name : NURUL BALKIS ZAMRI		
Date: 11/03/2022	Date: <i>11/3/2022</i>			Date : <i>11/03/2022</i>		

REWORK INSTRUCTION

DESCRIPTION: Misalignment printing



VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Doc. No.
Rev.

06

DATE :	10/03/2022
REF :	HW3SD100
LOT NO. :	A22714

SHOP PACKET QTY (pes) :
 CUSTOMER : PROJECTMED TOMASZ SUROWIEC (POLAND)
 I.O NO. : IOPRO/00458@01

DATE :	2016
CUSTOMER :	PROJECTMED TOMASZ SUROWIEC (POLAND)
I.O NO. :	IOPRO/00458@01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		RECEIVED BY
							ISSUED	CONSUMPTION	
1									
2			N/A					N/A	
3									
4									

(3) OVER WRAPPING AND CARTON PACK			
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.
1	P0100506	LBH-001-PL-R1 : EYEMARK - Hydrogen 500ml Polish Label, Size: 210mm X 71mm (Roll Form), White PP + Gloss Lamination (6 colors)	118C220202 2020 #N/A
2			
3			
4			

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

ISSUED BY (MM) :
 Signature :
 Name : FIRDAUS
 Date : 10/03/2022

VERIFIED BY (PR) :
 Signature :
 Name :
 Date :

Signature :
 Name : FIRDAUS
 Date : 10/03/2022