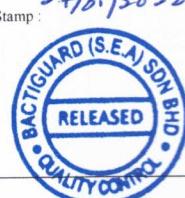


27/201

SHOP PACKET - EASW

REFERENCE	HW3SD100	ODR. QTY (PCS)	1,824	RS: 2 + 1(QC TEST)	ISSUED DATE	15/01/2022
ITEM CODE	H0100001	PACK SIZE	24/BOX		LOT NO.	A21509
ITEM DESCRIPTION	Hydrocyn Aqua, 500ml (Bottle Cap Closure)	CUSTOMER	VMD (MALAYSIA)		MFG. DATE	15/01/2022
		ODR. NO	A105		EXP. DATE	2024-01
PREPARED BY	NAME : NUR SHAHIRA DATE : 15/01/2022	VERIFIED BY	NAME : RATNASEGARAN DATE : 15/01/2022		INT. ORDER	IO/VMD/130122/01
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 :	8:00pm 24-01-22 8:15 Am 25-01-22	1827	1827	Nil	Roshini 8:15am 25/01/2022	TANK 1000Lpb 03HBA240122016
UDI PRINTING (Label/Box/Carton)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :	11:30 AM 25-01-22 4:30 PM 25-01-22					
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	1:30 PM 25-01-22 4:30 PM 25-01-22	1827	1819	8	SARAH (1102)	Roshini 4:30pm 25/01/22 -8 Blue cap reject replace with new cap
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	1:35 PM 25-01-22 4:30 PM 25-01-22	1827	1820	7	Netra (1103)	Roshini 4:30pm 25/01/22 -7 Label reject replace with new label
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	1:35PM 25-01-22 4:30 PM 25-01-22	1827	1827	Nil	Netra (1103)	Roshini 4:30 pm 25/01/2022
CAP SEALING (Applicable for 100mL)						
TIME START : DATE : TIME COMPLETE : DATE :				NA		
BOX PACKING & PRINTING (Applicable for 100ml only)				NA		
TIME START : DATE : TIME COMPLETE : DATE :						
MANUAL UDI LABELLING (Applicable for 100 mL & Bags only)				N/A		UDI NOT REQUIRED FOR THIS LOT
TIME START : DATE : TIME COMPLETE : DATE :						
FINAL CONTROL						
TIME START : DATE : TIME COMPLETE : DATE :	1:40 PM 25-01-22 4:30 PM 25-01-22	1827	1827	Nil	Netra (1103)	Roshini 4:30 pm 25/01/22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	11:45 am 26-01-22 3:30 PM 26-01-22	76 Ctn	76 Ctn	111	FAZLI 1054 HEROI 1055 Roshini (1088)	Nurin 26/1/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :				N/A		UDI NOT REQUIRED FOR THIS LOT

QUANTITY PRODUCED :	1827 Wts	
QUANTITY FOR QC / RETAIN SAMPLE :	223 16H	
SHIPMENT QUANTITY PCS / CTNS :	1826 Wts / 76 Ctns	
FINAL SHIPMENT DATE :	_____	
COMPLETE/ PARTIAL :	COMPLETE	PARTIAL

Checked by (PR), Signature : Name : Roshini Date : 26/1/22	Approved by (QA), Signature : Name : Rohamza Utman Date : 27/1/2022	Released by (QC), Signature : Name : MARTINI Designation : QC DEPT Date : 27/01/2022 Stamp : 
Remarks:		

VIGILENZ®

ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)

Doc. No QC-LC002
Rev. 00

Item Description	<i>Hydrogen Peroxide (Bottle cap closure)</i>		
Reference	<i>Hu35 DIVO</i>		
Lot No.	<i>A21509</i>		

No.	Checklist	Yes	No	Performed by (Signature / Date)	Verified by QC (Signature / Date)	Remarks	Responsibility
1	Flush machine HD-a01 with approximately 20L of RODI water & 10L of EASW solution before each production batch	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Kyawdaw 25/01/22</i>	<i>Perry 25/01/2022</i>	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				<i>Perry 25/01/2022</i>	N/A	
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"/>	<i>Tonyang 25/01/22</i>	<i>Perry 25/01/2022</i>	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"/>	<i>Tonyang 25/01/22</i>	<i>Perry 25/01/2022</i>	N/A	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:

1(3)

Reference / Lot No.	Hydrogen Aug 20ml (Bottle cap closure)	Doc Id:	QC-IP002-09	Issue Date:

Order Qty	A 21 509
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
10/10	520 ml	✓	✓	✓	✓	PASS
1/1000	520 ml	—	✓	✓	✓	FAIL
1/500	520 ml	—	✓	✓	✓	FAIL
1/300	520 ml	—	✓	✓	✓	FAIL
1/300	520 ml	—	✓	✓	✓	FAIL
1/300	520 ml	—	✓	✓	✓	FAIL
1/300	520 ml	—	✓	✓	✓	FAIL
1/317	520 ml	—	✓	✓	✓	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
10/10	✓	✓	✓	✓	FAIL
1/600	✓	✓	✓	✓	FAIL
1/100	✓	✓	✓	✓	FAIL
1/300	✓	✓	✓	✓	FAIL
1/100	✓	✓	✓	✓	FAIL
1/317	✓	✓	✓	✓	FAIL

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

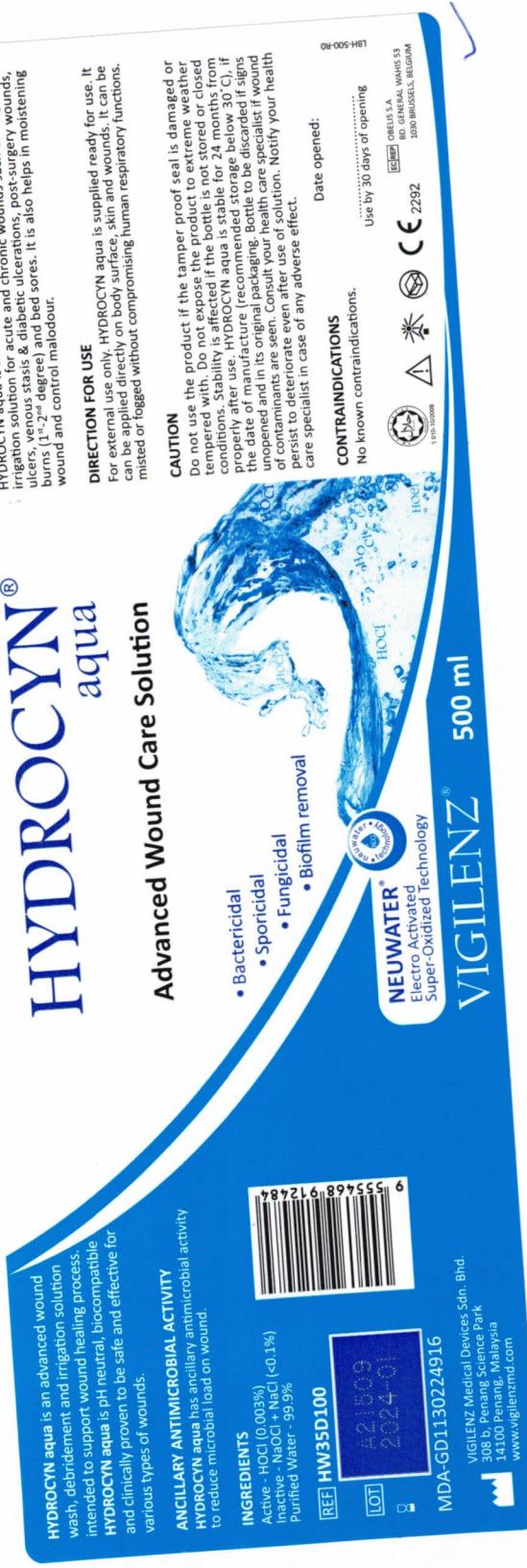
Item Description	Reference / Lot No.	Order Qty	Volume Specification

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	Issue Date: 15/1/2021	Page: 2(3)
Document type: FORM	Doc Id: QC-IP002-09			

C. Attachment (First Printed Label)



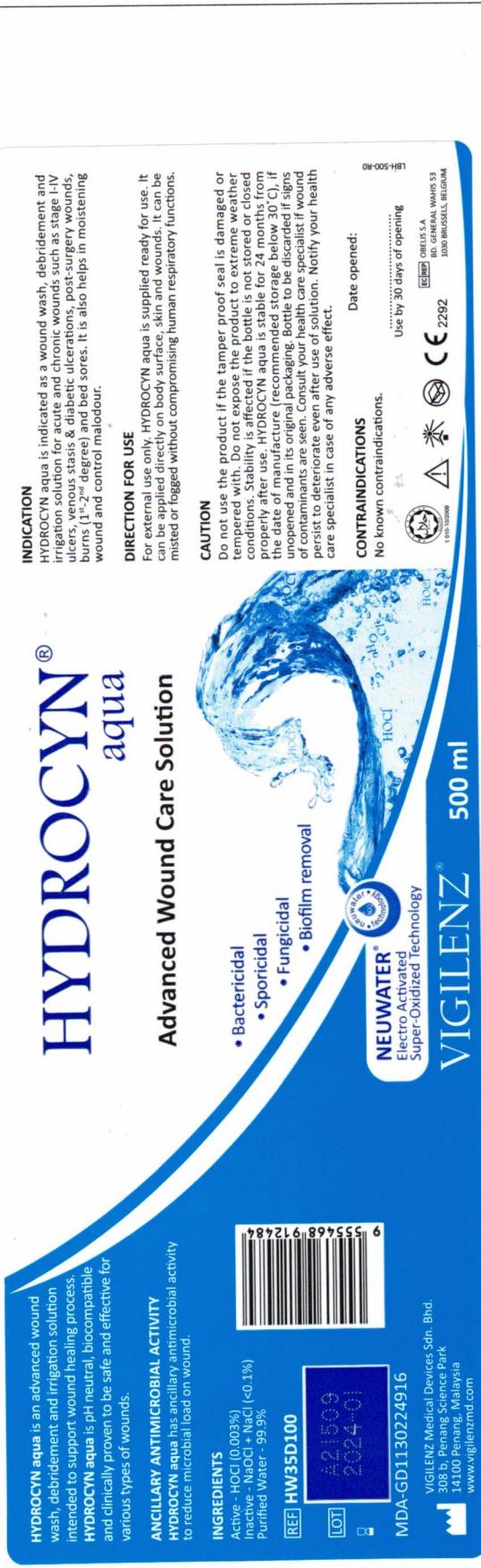
PASS

FAIL

Inspected by : Roly
Name : ROSHNI
Date : 25/01/2014

IN-PROCESS INSPECTION RECORD ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW) FORM	
Document type: FORM	Doc Id: QC-IP002-09

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 is 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 tampered 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 (recommendation) and 30 months from 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.

Use by 30 days of opening

ECER: 01054
010 GENERAL WASHES S3
TOE BRUSSELS, BELGIUM

Date opened:

Inspected by : Roy
Name : Pozhil
Date : 25/01/2021

Disposition of the Lot : PASS FAIL

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 : Huws D100
 LOT NO. : A91509

QTY. PRODUCED (pcs) : 1827
 RETAIN SAMPLE QTY. (pcs) : 2

No.	Inspection Criteria	Sampling Details	Sample Size	AQL			Results	Status
				Accept	Reject	Accept		
1	Legible and clean printing of label.	S3, 0.15	80	0	1	0	80	Pass
2	Free from contamination, deformed or damaged on packaging.	S1, 0.15	80	0	1	0	80	Pass
3	Proper sealing and no leaking.	S3, 0.15	80	0	1	0	80	Pass
4	Free from contamination / particle / foreign materials on product solution.	S3, 0.15	80	0	1	0	80	Pass
5	Correct volume filled (against reference sample).	S2, 0.15	80	0	1	0	80	Pass

Remarks : N/D

Approved By : Z. Jangid
 Name : K. K. Wali
 Date : 25/01/22

Inspected By : Rajiv
 Name : Rajiv
 Date : 25/01/22

VIGILENZ®

RAW MATERIAL LOADING FORM (RMLF)

Rev.

DATE :	20/01/2022
REF :	HW5SD100
LOT NO. :	A21509

SHOP PACKET QTY (pcs) : 1824
 CUSTOMER : VMD (MALAYSIA)
 LOT NO. : IOVMD130122/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	QUANTITY (pes)		RECEIVED BY
							ISSUED	CONSUMPTION	
1	P0100242	500ml HDPE Plastic Container (New Version)	(w Vigilenz Logo & Dropper Stopper, Can fit with Pump Nozzle & Blue cap)	H010211101	pcs	1827		1827	✓ Lengqiang
2	P0100200	Blue Cap for 500ml HDPE Plastic Container	0	H020210601	pcs	1827		1827	✓ Lengqiang
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078211101	pcs	1827		1827	✓ Lengqiang
4	N/A	STOCK SOLUTION	N/A	03H1824010206	ltr	950		950	✓ Lengqiang

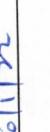
(3) OVER WRAPPING AND CARTON PACK

NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	ITEM DESCRIPTION 1			LOT NO.	QTY REQUIRED (pes)	RECEIVED BY
						ITEM CODE	ITEM DESCRIPTION 1	LOT NO.			
1	P0100679	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H165211103	76	✓ Inclue						
2	P0100680	500ml Hydrocyn Aqua carton -469L X 315W X 219H (BAF)	H065211103	76	✓ Inclue						
3		#N/A	#N/A								

(4) SPECIAL REQUIREMENT

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

ISSUED BY (MM) : 
 Signature : 
 Name : Lovin
 Date : 20/01/2022

VERIFIED BY (PR) : 
 Signature : 
 Name : DPM TECHNICAL
 Date : 26/11/22

VIGILENZ®

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

Doc No.	QC-PC00,
Rev.	06

Description	Hydrogen Peroxide 500 ml (Bottle Cap closure)	Reference No.	HW86D100	Date of Inspection	26/01/2022
Lot No.	A21509	Sample Size	1000 ml		

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
pH Spec: 6.50 - 8.00	ORP (mV) Spec: ≥ 850	FAC (ppm)		Test Disposition (PASS / FAIL)	
		Instrument	Result	Result	Instrument
7.00	ORP 78	850	850	11	0.80

RO water and product bioburden meeting the acceptance criteria.

Remarks : *N/P*

Disposition of the Lot : RELEASE ON-HOLD

Analyzed By : *Raj*
 Name : *Postma*
 Date : *26/01/2022*

Approved By : *S. Srinivas*
 Name : *KARTHIK*
 Date : *26/01/2022*



VIGILENZ®

REWORK INSTRUCTION

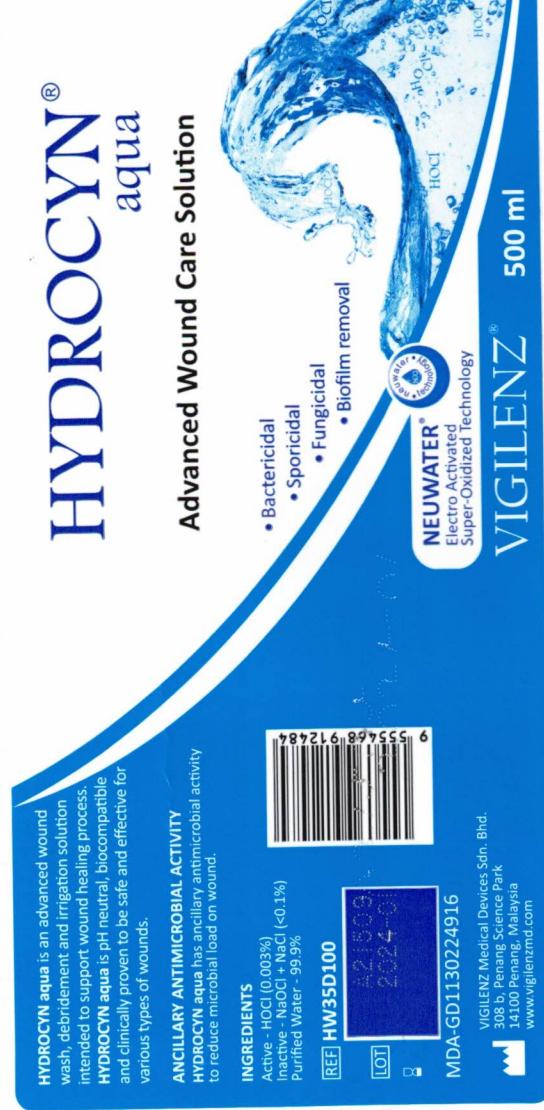
Doc. No PR-RI001

Rev 04

Rework Instruction No. : R1-PM12-22024					
Reference Code	HW35D100	Lot No.	A21509	Lot Quantity (pcs)	1827
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>Netra</i>				
Required Tools	N/A				
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)
1) Segregate the affected bottles	<i>Caujana 25/01/22</i>	All the bottles were verified			<i>Poly 25/01/22</i>
2) Remove the damage labels (Misalignmant printing)	<i>Caujana 25/01/22</i>	All the labels were removed from the bottles			<i>Poly 25/01/22</i>
3) Replace with new labels	<i>Caujana 25/01/22</i>	New labels were replaced			<i>Poly 25/01/22</i>
4) Re-print again the Expiry date and Lot number at correct position	<i>Caujana 25/01/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Poly 25/01/22</i>
5) Proceed to Final Control Process	<i>Caujana 25/01/22</i>	Verified in Final Control process and complies with all the specifications			<i>Poly 25/01/22</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> Name : MR.RATNA	Acknowledge By : <i>[Signature]</i> Name : MARTINI BINTI GHAZALI	Approved By : <i>[Signature]</i> Name : MR.JEEVANEND			
Date: 25/01/2022	Date: 25/01/22	Date : 28/1/2022			

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 is also helps in moistening wound and control malodour.

DIRECTION FOR USE
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CAUTION
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CONTRAINdicATIONS
No known contraindications.

LBH-500-H0

Use by 30 days of opening
EUROPE
VIGILENZ
GENERAL WAARS 53
1020 BRUSSELS, BELGIUM

REF 2292

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