

SHOP PACKET - EASW

REFERENCE	HW36D100	ODR. QTY	492	RS: 2 + 1(QC TEST)	ISSUED DATE	02/03/2022
ITEM CODE	H0100007	PACK SIZE	12/BXS	LOT NO.	A22900	
ITEM DESCRIPTION	Hydrocyn Aqua, 1000ml (Bottle Cap Closure)	CUSTOMER	PROJECTMED TOMASZ SUROWIEC	MFG. DATE	02/03/2022	
PREPARED BY	NAME : NUR SHAHIRA DATE : 02/03/2022	VERIFIED BY	ODR. NO. A199	EXP. DATE	28/02/2024	
UDI-DI NO. (1st Packaging) - Bottle/Box/Bag	07333330201223	UDI-DI NO. (2nd Packaging) - Carton	17333330201220	UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)17333330201220	(11)02032022
UDI-PI NO. (1st Packaging) - Bottle/Box/Bag	(01)07333330201223	(11)02032022	(10)A22900	UDI-PI NO. (2nd Packaging) - Carton	(17)28022024	(10)A22900

PROCESS	INPUT BOTTLE	OUTPUT BOTTLE	REJECT	OPERATOR	IPQC APPROVAL	REMARKS
STOCK SOLUTION PREPARATION						
TIME START : DATE : TIME COMPLETE : DATE :	4:30PM 08-03-22	495	495	Nil	Roshni 893	Tank 500L T5 Tank 1000L T6 03/03/2022 03H8080322070
UDI PRINTING (Label/Box/Carton)						
TIME START : DATE : TIME COMPLETE : DATE :	5:35 PM 10-03-22	497	497	4	Nisya 980	4pcs printing not clear and replace new label printing.
SOLUTION FILLING & CAPPING						
TIME START : DATE : TIME COMPLETE : DATE :	9:30 AM 10-03-22	495	495	Nil	Roshni 10/03/2022	6:30 PM 10/03/2022
LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	3:45 PM 12-03-22	495	497	9	E19(932)	Roshni 5:25 PM 12/03/2022
PRINTING LOT NUMBER						
TIME START : DATE : TIME COMPLETE : DATE :	3:45 PM 12-03-22	495	495	Nil	E19(932)	Roshni 5:20 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 :	3:45 PM 12-03-22	495	495	Nil	E19(932)	Roshni 7:05 PM 12/03/22
CARTON PACK						
TIME START : DATE : TIME COMPLETE : DATE :	3:15 pm 14-03-22	41	41	Nil	FASLI 1054 HEROI 1053 ZABIN 1088	Jinvar 14/03/22
UDI LABELLING						
TIME START : DATE : TIME COMPLETE : DATE :	3:15 pm 14-03-22	41	41	Nil	FASLI (1054) HEROI (1053)	Jinva 14/03/22

QUANTITY PRODUCED : 495 btl
 QUANTITY FOR QC / RETAIN SAMPLE : RS 2 + 1btl
 SHIPMENT QUANTITY PCS / CTNS : 492 btl / 41 ctn
 FINAL SHIPMENT DATE :
 COMPLETE / PARTIAL : COMPLETE PARTIAL

Checked by (PR), Signature : <i>[Signature]</i> Name : Roshni Date : 15/3/22	Approved by (QA), Signature : <i>[Signature]</i> Name : Rohamiza Othman Date : 22/3/2022	Released by (QC), Signature : <i>[Signature]</i> Name : ARSHAT Designation : IPQC SUPERVISOR Date : 15/3/2022 Stamp : <i>[Stamp]</i>
Remarks:		





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

Item Description	Hydrogen Peroxide 1000 ml (Bottle cap closure)
Reference	HWWB6D00
Lot No.	A13900

No.	Checklist	Yes	No	Performed by (Signature / Date)	Verified by QC (Signature / Date)	Remarks
1	Flush machine HD-01 with approximately 20L of RODI water & 10L of EASW solution before each production batch	<input type="checkbox"/>	<input type="checkbox"/>	M <i>10/03/2017</i>	N/h <i>10/03/2017</i>	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"/> i) Starwheel <input checked="" type="checkbox"/> ii) Nozzle <input checked="" type="checkbox"/> iii) Stopper Insertor <input checked="" type="checkbox"/> iv) Cap Dispenser <input checked="" type="checkbox"/> v) Cap Pusher	<input type="checkbox"/>	<input type="checkbox"/> <i>10/03/2017</i>	<input type="checkbox"/> <i>10/03/2017</i>	Technician <i>10/03/2017</i>

No.	Checklist	Yes	No	Performed by (Signature / Date)	Verified by QC (Signature / Date)	Remarks
1	Flush machine HD-01 with approximately 20L of RODI water & 10L of EASW solution before each production batch	<input type="checkbox"/>	<input type="checkbox"/>	M <i>10/03/2017</i>	N/h <i>10/03/2017</i>	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"/> i) Starwheel <input checked="" type="checkbox"/> ii) Nozzle <input checked="" type="checkbox"/> iii) Stopper Insertor <input checked="" type="checkbox"/> iv) Cap Dispenser <input checked="" type="checkbox"/> v) Cap Pusher	<input type="checkbox"/>	<input type="checkbox"/> <i>10/03/2017</i>	<input type="checkbox"/> <i>10/03/2017</i>	Technician <i>10/03/2017</i>
3	Working area are cleaned and free from any dirt / dust and foreign particles	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Conjanu</i> <i>10/03/2017</i>	<i>Prajy</i> <i>10/03/2017</i>	Production <i>NP</i>
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>Conjanu</i> <i>10/03/2017</i>	<i>Prajy</i> <i>10/03/2017</i>	Production <i>NP</i>

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

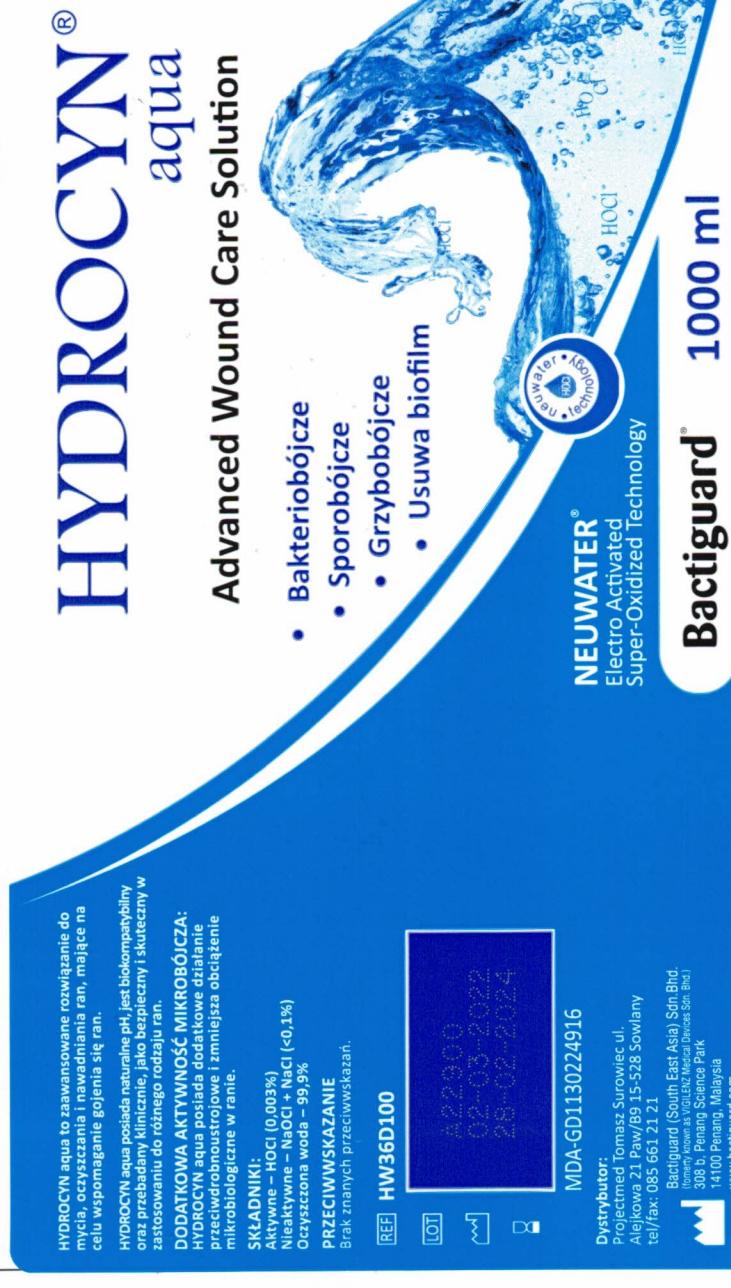
Item Description	Hydrogen Dewar 1000 ml (Bottle cap closure)
Reference / Lot No.	HW86D100 / P22900
Order Qty	491
Volume Specification	1030 ± 20 ml

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)	
Document type:	Doc Id: QC-IP002-09	Issue Date: 15/11/2021

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 AKTYWNNOŚĆ MIKROBÓJĄCA:
HYDROCYN aqua posiada dodatkowe działania przeciwbakterioustrojowe i zmniejsza obciążenie mikrobiologiczne w ranie.

SKŁADNIKI:

Nieaktywne - HOCl (0,003%) | NaCl (<0,1%)
Oczyszczona woda - 99,9%

PRZECIWUMSKAŻANIE
Brak znanych przeciwwskazań.

REF: HW36D100

0470733333020-1223

(41)02032022(17)28022024(10)A22900

Data otwarcia:

Użyć w ciągu 30 dni po otwarciu

LBH-015-PL-RI

OBLIS S.A.
BD. GENERAL WAHIS 53
1030 BRUSSELS, BELGIUM



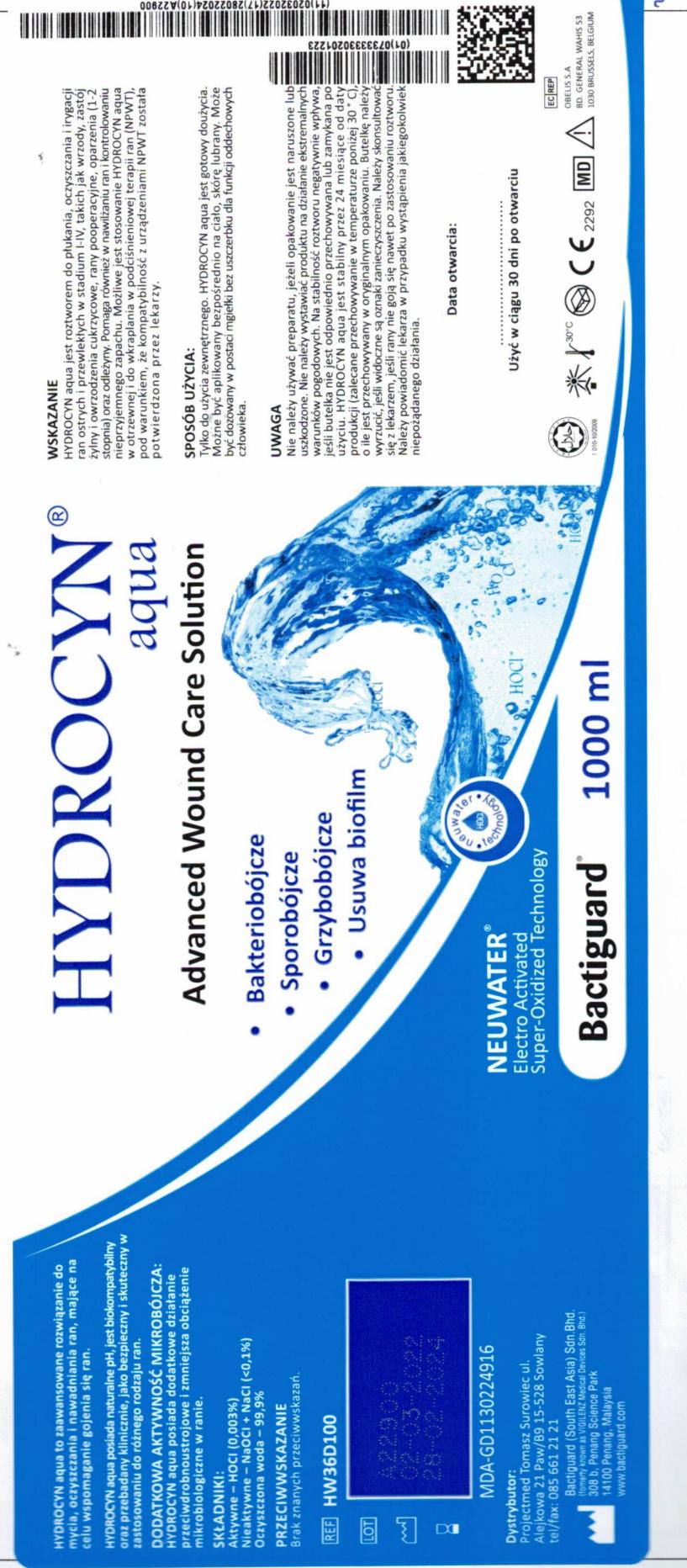
Disposition of the Lot : PASS FAIL



Inspected by : Rajesh
Name : Rajesh
Date : 10/11/2022

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: 3 (3)

D. Attachment (Last Printed Label)



Inspected by : Piotr Rosiński
 Name : Piotr Rosiński
 Date : 14/03/2017

Disposition of the Lot : PASS FAIL

VIGILENZ®	FINAL CONTROL TEST REPORT - ELECTRO ACTIVATED SUPER-OXIDIZED WATER (EASW)		
ITEM DESCRIPTION	: <i>Hydrogen Aqua, 1000ml</i>	QTY. PRODUCED (pcs)	: <i>445</i>

REFERENCE : *HWS6D00*
 LOT NO. : *A11900*

RETAIN SAMPLE QTY. (pcs) : *2*

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

Remarks : *N/A*

Approved By : *Roshni*
 Name : *M. Roshni*
 Date : *15/08/2022*

Inspected By : *Roshni*
 Name : *M. Roshni*
 Date : *12/03/2022*

Doc. No. QC-FC004
 Rev. 09

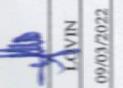
DATE :	09/03/2022
REF :	HW3GD100
LOT NO. :	122900

SHOP PACKET QTY (pes)	492
CUSTOMER	PROJECTMED TOMASZ SUROWIEC (POLAND)
LO NO.	IOPRO/004582/01

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	REQUIRED	ISSUED	QUANTITY (pes)		RECEIVED BY
								CONSUMPTION	RECEIVED	
1	P0100799	1000ml HDPE Plastic Container	0	H01C210601	pes	495	495	495	495	✓ Tomasz
2	P0100200	Blue Cap for 250ml/500ml/1000ml HDPE Plastic Container	0	H020210601	pes	495	495	495	495	✓ Tomasz
3	P0100357	DROPPER STOPPER	(500ML & 250ML BOTTLE)	H078210701	pes	495	495	495	495	✓ Tomasz
4		STOCK SOLUTION		✓ 03/18/2020 03/18/2020	ltr	509	509	509	509	✓ Tomasz

(3) OVER WRAPPING AND CARTON PACK										
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	LOT NO.
1	P0100587	LBH-015-PL-R0 - Hydrocyon 1000ml Label (Polish), Size: 250mm x 110mm, Material: White PP + Gloss	L18F220301		496	✓ Tomasz	H103220201	41	✓ Tomasz	
2		#N/A					P0100583			H041210501
3		#N/A					P0100584			H042202021

(4) SPECIAL REQUIREMENT										
NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	LOT NO.	QTY REQUIRED (pes)	RECEIVED BY	LOT NO.
5		#N/A					P0100324			#N/A
6		#N/A								
7		#N/A					#N/A			

ISSUED BY (MM): 
 Signature: LAVIN
 Name: LAVIN
 Date: 09/03/2022

VERIFIED BY (PR): 
 Signature: Projectmed
 Name: Projectmed
 Date: 15/3/2022

Doc ID: QC-OI001-04	Issue Date: 09/02/2022	Page: 2(2)
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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 VIGILLENZ Medical Devices Sdn Bhd)
308b, Jalan Perindustrian Bukit Minyak 18,
Penang Science Park, 14100 Penang, Malaysia.



REF HW36D100

LOT A22900

EXPIRY 28-02-2024



(0111733330201220(11)02032022(17)28022024(10)A22900

*Only print this sheet for products with UDI

Inspected by : Jinika
Name : K.Nikini
Date : 18/03/2022

Page 2

Verified by : Jinika
Name : K.Nikini
Date : 18/03/2022

VIGILENZ®

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

Doc No.	QC-PC007
Rev.	06

Description	Hydrogen Peroxide, 1000ml (Bottle Cap closure)	Reference No.	HWS62100	Date of Inspection	14/03/2021
Lot No.	A12900	Spec:	≥ 850	Sample Size	1 bottle x 1000 ml

Release Criteria:

Analysis of Electro Activated Super-Oxidized Water (EASW)					
Result	Instrument	Result	ORP (mV)	FAC (ppm)	Test Disposition (PASS / FAIL)
			Spec: 6.50 - 8.00	Spec: ≥ 850	Instrument
7.28	Q1-78	861	Q1-67	120	Q1- 80 Pass

- RO water and product bioburden meeting the acceptance criteria.

Remarks : N/A

Disposition of the Lot : RELEASE ON-HOLD



Approved By : John
Name : John
Date : 15/3/2022

Analyzed By : Linh
Name : Linh
Date : 14.3.22

VIGILENZ®

REWORK INSTRUCTION

Doc. No	PR-RI001
Rev	04

Rework Instruction No. : R1-PM12-22061						
Reference Code	HW36D100	Lot No.	A22900	Lot Quantity (pes)	495	Quantity Affected (pes)
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>Era</i>					
Required Tools	N/A					
Rework Step	Verified by (PR)	Inspection Details			Verified by (QAQC)	
1) Segregate the affected bottles	<i>Cayana 12/03/22</i>	All the bottles were verified			<i>Rey 12/03/22</i>	
2) Remove the damage labels (Misalignmant printing)	<i>Cayana 12/03/22</i>	All the labels were removed from the bottles			<i>Rey 14/03/22</i>	
3) Replace with new labels	<i>Cayana 12/03/22</i>	New labels were replaced			<i>Rey 14/03/22</i>	
4) Re-print again the Expiry date and Lot number at correct position	<i>Cayana 12/03/22</i>	Expiry date and Lot number (corresponds to the shop packet) were printed at the correct position			<i>Rey 12/03/22</i>	
5) Proceed to Final Control Process	<i>Cayana 12/03/22</i>	Verified in Final Control process and complies with all the specifications			<i>Rey 12/03/22</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>M.A</i>	Acknowledge By : <i>M.A</i>			Approved By : <i>ZB</i>		
Name : MUHD. ARIFUDEEN	Name : MARTINI BINTI GHAZALI			Name : NURUL BALKIS ZAMRI		
Date: 12/03/2022	Date: 14/03/2022			Date : 14/03/2022		

