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<p>Checked by (PR),  Signature : <u><i>[Signature]</i></u>  Name : <u>DAVID E. CAPAN</u>  Date : <u>05/19/22</u></p>	<p>Approved by (QC),  Signature : <u><i>[Signature]</i></u>  Name : <u>MARK TIM</u>  Date : <u>05/21/2022</u></p>
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Page 1 of 2



LABEL APPROVAL

**Οδηγίες χρήσης:** Βεβαιωθείτε πρώτα ότι έχει καθαριστεί η πληγή. Εφαρμόστε τη γέλη απευθείας στην πληγή σε κάθε αλλαγή επιδέσμου του τραυματία. Μόνο για εξωτερική χρήση. Μετά το άνοιγμα της συσκευασίας, θα πρέπει να χρησιμοποιείται το σύνολο του περιεχομένου.

**Συστατικά:** Κεκαθαρμένο ύδωρ, Υποχλωριώδες νάτριο (0,05%), Νιθιο-Μαγνήσιο-Νάτριο Πυριτικό και Χλωριούχο Νάτριο.

Bactiguard (South East Asia) Sdn. Bhd.  
(formerly known as VIGILENZ Medical Devices)  
308b, Penang Science Park, 141000 Penang, M

EC REP: ORELS S.A. BD. GENERAL WWHIS 53, 10301 BRUSSELS, BELGIUM

CE 2292

REF: BW4

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Αρ. Γνωστοποίησης ΕΟΦ:  
130619/23-12-2021.

REF: BW4CB900



CE 2292

LOT: B20400  
EXP: 2023-08



**Bactiguard<sup>®</sup>**  
**WOUND CARE**  
**GEL**

100g

**Bactiguard<sup>®</sup>**

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.

Διανομέας: LIFECYN AE  
Καζάντζακη 4 & Αγ. Παντελεήμονος  
13561 Άγιοι Ανάργυροι, Αττική  
Τηλ.: +(30) 210 8313616 email: info@lifecyn.com

EC REP: ORELS S.A. BD. GENERAL WWHIS 53, 10301 BRUSSELS, BELGIUM

**WOUND CARE**

Καταπραύντική & Βακτηριοστατική δράση

**Γέλη 100g**

REF: BW4CB900

LOT: B20400

Qty: 6 pcs / box

Weight: 100 g / pc

**Bactiguard<sup>®</sup>**

⊗

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Handwritten: Poly 22/12/22







File:

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 1(3)


Reference / Lot No.	BW4CB900 / B20400
Order Qty.	144

**A. Before Filling**

Batch No.	Container No.	pH (9.00 – 10.50)	FAC (100 – 200 ppm)	Viscosity (8,000 – 10,000 cps)	Gel is clear and free from contamination	Test disposition (PASS / FAIL)
6180702203	613	9.25	comply	9491	✓	pass
6180702204	614	9.25	comply	9491	✓	pass

**B. Tube Labelling**

Sampling / Frequency	Printed label is clear and legible	Reference no. corresponds to Shop Packet and approved artwork	Correct positioning of labelling	Test disposition (PASS / FAIL)
5 / 5	✓	✓	✓	pass
1 / 5	✓	✓	✓	pass
2 / 5	✓	✓	✓	pass
3 / 5	✓	✓	✓	pass
4 / 5	✓	✓	✓	pass
5 / 5	✓	✓	✓	pass

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		 Bactiguard	
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 2(3)


### C. Filling Process

Sampling / Frequency	Weight of Sample					Leak Test	Test disposition (PASS / FAIL)
	1	2	3	4	5		
	Specification: 15g (16.5 – 17.8g) / 30g (31.6 – 33.3g) / 50g (51.9 – 53.4g) / 100g (102.8 – 104.7g)						
5/5	104.31	104.00	102.83	103.23	103.96	✓	pass
1/5	103.11	104.09	103.12	103.22	104.27	✓	pass
2/5	103.09	103.42	103.22	103.72	104.00	✓	pass
3/5	103.99	104.02	103.28	104.01	103.86	✓	pass
4/5	103.03	103.60	103.88	102.99	103.28	✓	pass
5/5	103.85	104.29	102.90	103.79	103.37	✓	pass

### D. Sealing and Cutting

Sampling / Frequency	Sealing is intact	No sharp edge and not slanted after sealing and cutting	Lot no. and expiry date on tube is correct as in Shop Packet and legible	Seal Width Specification: (15g : 4-6mm) (30g/ 50g/ 100g : 6-8mm)	Leak Test	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

File:

QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL			
Document type: FORM	Doc Id: QC-IP004-01	Issue Date: 15/11/2021	Page: 3(3)

### E. Printing on Primary Packaging

Sampling / Frequency	Print information must be clear / legible and conforms to specifications as stated in approved artwork	Lot no. and expiry date are corresponding to Shop Packet and approved artwork	Correct position of printing	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	pass
1/5	✓	✓	✓	pass
2/5	✓	✓	✓	pass
3/5	✓	✓	✓	pass
4/5	✓	✓	✓	pass
5/5	✓	✓	✓	pass

### F. Primary Packaging

Sampling / Frequency	Product is properly pack in primary packaging	Ref. no., lot no. and expiry date on primary box is correct and legible	Special requirement printing is clear and legible	Presence of secure stickers on both opening sides of the primary box	Presence of hologram sticker on the primary box	Test disposition (PASS / FAIL)
5/5	✓	✓	✓	✓	✓	pass
1/5	✓	✓	✓	✓	✓	pass
2/5	✓	✓	✓	✓	✓	pass
3/5	✓	✓	✓	✓	✓	pass
4/5	✓	✓	✓	✓	✓	pass
5/5	✓	✓	✓	✓	✓	pass

### G. Conclusion

Overall in – process inspection: (PASS / FAIL)

Inspected By : Poly  
 Name : PESHNE  
 Date : 23/2/2022



VIGILENZ®

## FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

Doc. No. :  
Rev. : 03

REF :

BW4CB900

QTY PRODUCED (pcs) :

147

LOT NO :

B20490

RETAIN SAMPLE QTY (pcs) :

3 pcs

No	Inspection Criteria	Sampling Details	Sample Size	AQL		Results		Status (PASS/FAIL)
				Accept	Reject	Accept	Reject	
1	Legible and correct printing of label.	S3,0.15	80	0	1	80	0	pass
2	Availability of Hologram and Secure Sticker.	S3,0.15	80	0	1	80	0	pass
3	Free from contamination, deformed or damaged on packaging.	S3,0.15	80	0	1	80	0	pass
4	Proper sealing and no leakage.	S3,0.15	80	0	1	80	0	pass
5	Correct quantity in secondary box packaging.	S3,0.15	80	0	1	80	0	pass

Remarks :

N/A

Inspected By :

Name :

Date :

Parij

DASHNI

23/02/2022

Approved By :

Name :

Date :

M. J. J.

MARTINI

23/2/2022



# RAW MATERIAL LOADING FORM (RMLF)

Doc. No.	PR-RM001
Rev.	06

SHOP PACKET QTY (pcs)	144	RS	9
CUSTOMER	BACTIGUARD AB (LIFECYN)		
LO NO.	IO/CYN/060505/01		

05/02/2022
BW4CB900
B20400

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pcs)		RECEIVED BY
						REQUIRED	ISSUED	
1	P0100727	100g Tubes with D40 White Color Screw-on Cap	Diameter 40 x 135 mm, White Colour Tube + neck, 5mm Tube Orifice with Aluminium Foil Seal, Open End	H11G210501	pcs	153	153	Kanyana
2	P0100804	White Nozzle Cap	0	H12G210701		306	306	Kanyana
3	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gm	800	800	Kanyana
4	C0100048	Sodium Hypochloride, 10% Available Chlorine	0	C023210701	ml	200	200	Kanyana
5	C0100024	Pure Dry Vacuum Salt (25kg)	-	C021210601	gm	20	20	Kanyana
6	N/A	STOCK SOLUTION	N/A	C030702203 C030702204	ltr	20	20	Kanyana

(3) OVER WRAPPING AND CARTON PACK						
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY	
1	P0100661	Gauze/Gel Carton-(L)388mm X (W)293mm X (H)305mm LR150/M/LR150 (BC FLUTE)	H114210801/2	2	<i>males</i>	
2	P0100767	V0047-0154; POF 5 Layer Shrink Film CF with perforation- Size: 12mic x 12" x 1667m; 1 rolls/carton	P092210801	NA	<i>males</i>	
3		#N/A				

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100896	LBWC-012-GR-R0 (100G - Gel Tube- GREECE), VIGLENZ0132; 110MM X 125MM; IN ROLL, TRANSPARENT PE, 4C + WHITE	LBES421101	154	<i>Kanjana</i>
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22210801	307	<i>Kanjana</i>
3	P0100806	LDPE ZIPPER BAG; Size: 0.05mm x 2" (opening) x 3" (L) USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	154	<i>Kanjana</i>

(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)		NA	
2		#N/A			

(2) PRODUCT PACKAGING					
NO	SYSTEM CODE	ITEM DESCRIPTION 1	LOT NO.	QTY REQUIRED (pcs)	RECEIVED BY
1	P0100896	LBWC-012-GR-RO (100G - Gel Tube- GREECE), VIGLEN20132; 110MM X 125MM; IN ROLL, TRANSPARENT PE, 4C + WHITE	LBES421101	154	Kanyana
2	P0100848	Secure-Secure Round Sticker for Gel Tube (20mm) Material: Breakable PVC, Printing: 1 colour (black) (30g, 50g, 100g)	LB22210801	307	Kanyana
3	P0100808	LDPE ZIPPER BAG, Size: 0.05mm x 2" (opening) x 3" (L) USE ONLY FOR GEL TUBE (30g, 50g AND 100g)	P806210701	154	Kanyana
4	P0100911	BWC-GEL INNER BOX 100g - BWC-005-GR-R0 GREECE	BGR320201		
5	P0100790	V09-BX024-00 - Hydrocyn Gel 100g (outer box) 300gm 1 Side Air Card, 237 x 84 x 168mm	PH02210701	13	Kanyana
6	P0100208	BLANK LABEL (Sharps Pad) Gauze/Gel SIZE: 85mm X 65mm	L190210801	13	Kanyana
7		#N/A			

ISSUED BY (MM)	VERIFIED BY (PR)
Signature : 	Signature : 
Name : LOVIN	Name : RAJASEKARAN



# GILENZ®

## PRODUCT RELEASE TEST REPORT – HYDROCYN aqua® GEL

Doc No. QC-PC008  
Rev. 02

Description	Background wound care gel		Reference No.	BW4CB900	Date of Inspection	24/02/2022
	Tube (100g)		Lot No.	B20400	Sample Size	1pc x 100g

### Release Criteria:

Packing Integrity				Visual Inspection	Chemical Testing		Test Disposition
Correct and legible printing of label	Proper sealing	Ability to dispense	Free from contamination/deformed/damaged	No leakage	Free from contamination / particles / foreign matters	pH (9.00 – 10.50)	FAC (100 – 200 ppm)
✓	✓	✓	✓	✓	✓	9.74	comply
							PASS / FAIL
							pass


✓ = Pass, X = Fail

Remarks: N/A

CONCLUSIONS: ☒ RELEASE

☐ ON-HOLD

Inspected By : Weh  
Name : Weh Weh  
Date : 24/02/22

Approved By :   
Name : A. ARTINI  
Date : 24/2/2022

