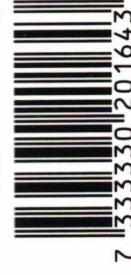




LABEL APPROVAL

Bactiguard<sup>®</sup>



7 333330 201643  
020 303  
2023-08

Αρ. Γνωστοποίησης ΕΟΦ:  
1306/9/23-12-2021.

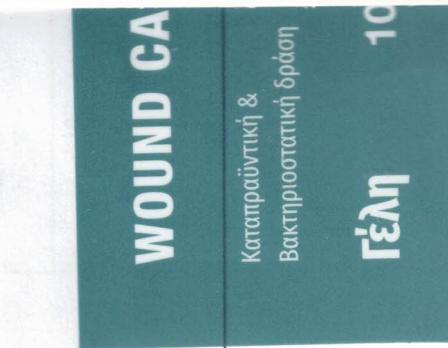
REF BW4CB900



€ 2292

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

100g



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.

BBWC-005-GR-RO

Διανομέας: LIFE CYC/N AΕ  
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13561 Αγίοι Ανάργυροι, Αττική  
Τηλ.: +(30) 210 8313616 email: info@lifecyn.com

[EC REP] OBESUS S.A. BD. GENERAL WAHIS 53, 1030 BRUSSELS, BELGIUM

WOUND CARE

Καταπραϋντική & Βακτηριοστατική δράση

Bactiguard<sup>®</sup>

Γέλη 100 g

Qty 6 pcs / box  
Weight 100 g / pc

Bactiguard<sup>®</sup>

✓ Bactiguard<sup>®</sup>



VIGILENZ®

## HYDROCYN aqua® GEL - RECORDS OF PREPARATION

卷之三

transfers

Date

Title:	QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL		
Document type:	FORM	Doc Id:	QC-IP004-01

Reference / Lot No.	B04C0900	/	B 20309
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)
G1B 09022201	G1	9.76	comply	9306	✓	pass
G1B 09022202	G2	9.76	comply	9306	✓	pass
				N/A		

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

Document type:  
FORM

Doc Id:  
QC-IP004-01

Issue Date:  
15/11/2021

Page:  
2(3)



Bactiguard

### C. Filling Process

Sampling / Frequency	Weight of Sample					Test disposition (PASS / FAIL)	
	1	2	3	4	5		
5/5	103.60 g	103.27 g	104.31 g	104.65 g	103.04 g	103.63 g	pass
1/5	104.64 g	104.15 g	103.23 g	104.25 g	104.19 g	104.09 g	pass
2/5	103.46 g	103.43 g	104.44 g	104.45 g	103.36 g	103.80 g	pass
3/5	103.40 g	103.90 g	102.82 g	102.89 g	102.84 g	103.18 g	pass
4/5	104.48 g	103.56 g	104.70 g	103.27 g	104.50 g	104.11 g	pass
5/5	103.16 g	104.16 g	101.53 g	104.22 g	104.56 g	104.13 g	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

Title: QC IN-PROCESS INSPECTION RECORD – HYDROCYN aqua GEL

Document type:  
FORM

Doc Id:  
QC-IP004-01

 Bactiguard	Issue Date: 15/11/2021	Page: 3(3)
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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) PASS

Inspected By : Rajy  
 Name : Rosent  
 Date : 22/11/2021

VIGILENZ®

## FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

Doc. No.	QC-FC006
Rev.	03

REF

LOT NO

BwycBqoo

БУЧІВОВ

QTY PRODUCED (pcs)

### RETAIN SAMPLE QTY (pcs)

117

3

No	Inspection Criteria	Sampling Details		AQL		Results		Status (PASS/FAIL)
		Sample Size	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:

Inspected By \_\_\_\_\_  
Name \_\_\_\_\_ Date \_\_\_\_\_

Approved By  
Name \_\_\_\_\_ Date \_\_\_\_\_

M. Martin 26/2/2021

# RAW MATERIAL LOADING FORM (RMLF)

Doc. No. PR-RM001  
Rev. 06

DATE :	05/02/2022
REF :	BW4CB900
LOT NO. :	B20309

SHOP PACKET QTY (pes) :  
CUSTOMER : BACTIGUARD AB (LIFECYN)  
LO/CYN/06/05/01

RECEIVED BY :	144
RS :	9

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	DESCRIPTION 2	LOT NO.	UOM	QUANTITY (pes)		CONSUMPTION	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	153	1 Canjano
2	P0100804	White Nozzle Cap	-	H12G210701	pc	306	306	306	1 Gaujana
3	C0100026	RHEOLOGICAL ADDITIVE (SUPBENT MP)	-	H080210801	gram	800	800	800	1 Gaujana
4	C0100048	Sodium Hypochlorite, 10% Available Chlorine	0	C023210701	ml	200	200	200	1 Gaujana
5	C0100024	Pure Dry Vacuum Salt (25 kg)	-	C021210601	gram	20	20	20	1 Gaujana
6	N/A	STOCK SOLUTION	N/A	B009023201 B1B09023202	ltr	20	20	20	1 Gaujana

## (3) OVER WRAPPING AND CARTON PACK

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

## (4) SPECIAL REQUIREMENT

NO.	SYSTEM CODE	ITEM DESCRIPTION 1	ITEM DESCRIPTION 2	LOT NO.	QTY REQUIRED (pes)	QTY REQUIRED (pes)	RECEIVED BY
4	P0100911	SWC GEL INNER BOX 100g - BWLC -005 -GR-RD GREECE	BGR320-20/	13	1	1	1
5	P0100790	V09-BX024-00 - Hydrocyan Gel 100g (outer box) 300gsm 1 Side Art Card, 237 x 84 x 168mm	PH02210701				
6	P0100208	BLANK LABEL (Shraps Pad/ Gauze' Gel) SIZE: 85mm X 65mm	L190210801	13	1	1	1
7		#N/A					

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

ISSUED BY (MM):  
Signature:  
Name:  
Date:

VIGILENZ®

## FINAL CONTROL TEST REPORT : HYDROCYN aqua® GEL

Doc. No.	QC-FC006
Rev.	03

REF : BWYCB900  
 LOT NO : B20309

QTY PRODUCED (pcs) :

144

RETAIN SAMPLE QTY (pcs) :

3

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 : Raj  
 Name : Roshni  
 Date : 23/12/22

Approved By : M. R. TIRUMALA  
 Name : M. R. TIRUMALA  
 Date : 26/12/2022

# VIGILENZ®

## PRODUCT RELEASE TEST REPORT - HYDROCYN aqua® GEL

Doc No.	QC-PC008
Rev.	02

Description	Back guard wound care , Gel tube 100g .	Reference No.	BWY1B900	Date of Inspection	23 / 02 / 2012
		Lot No.	B20309	Sample Size	100g 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 )	PASS / FAIL
✓	✓	✓	✓	✓	✓	9.18	compliant	pass

✓ = Pass, X = Fail

Remarks: N/P

- CONCLUSIONS:  RELEASE  
 ON-HOLD

Inspected By : Poly  
Name : Posting  
Date : 23/02/2012



Approved By : Z. Alif  
Name : MARTIN  
Date : 23/2/2012