

Manufacturer:  **HELSINN HEALTHCARE S.A.**

Via Pian Scairolo 9 – Pambio Noranco – 6915 Lugano – CH

BATCH RELEASE**European Representative:** N.A.**Product:**

Product	Outer 21PZ Gelclair 15 ml
Code	0HEL70020315
Batch Number	106111
Number of Units	1'659 (of which 3 for Internal Samples)
Manufacturing Date	15.03.2021
Expiry date	2024/02

Classification:**Class IIa** (according to Annex IX Rule 4 of 93/42 EEC - as amended by 2007/47 EC).**Conformity Assessment Route:**

Annex V + Annex VII

Standards applied*:

EN ISO 13485; EN ISO 14971; EN 1041; EN ISO 15223-1; EN ISO 10993 – 1; EN ISO 16408; EP; USP; F.U..

*When not otherwise specified, the Standard edition in force at the time of signature is to be intended.

Notified Body:

TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany (NB 0123)

EC Certificate(s):

G2 070849 0009; exp. 2024-05-26

Deviation/NC	<input type="checkbox"/> YES (n.°.....)	<input checked="" type="checkbox"/> NO
Conformity of Supplier CoAs	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Conformity Batch Record Abstract	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO

Quality Assurance Signature: 

Lugano (CH), Date: 26/04/2021

DECLARATION OF CONFORMITY**In Accordance with Council Directive 93/42/EEC as amended by Directive 2007/47/EC**

We hereby declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC, as amended by 2007/47 EC, for medical devices.

The present product was manufactured, packaged and controlled according to the requirements defined in the relevant Technical Documentation, applying a Quality System in compliance with 93/42 (as amended by 2007/47 EC) annex V and annex VII and with EN ISO 13485.

The present lot can be released to market. All supporting documentation is retained under the premises of the manufacturer.

Helsinn Healthcare SA, as manufacturer, is exclusively responsible for the Declaration of Conformity.

Management Signature: 

Lugano (CH), Date: 26/04/2021

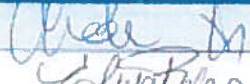


HELSINN HEALTHCARE S.A.

Via Pian Scaiolo 9 – Pambio Noranco – 6815 Lugano – CH

BATCH RECORD ABSTRACT

Please complete this form when you do not send the whole batch record to HELSINN HEALTHCARE for the authorization to release the batch

MANUFACTURING SITE	BIOKOSMES	HELSINN HEALTHCARE CHECK
Helsinn Healthcare Purchase Order #	20000044	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Biokosmes Order Confirmation #	20/00833	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Helsinn Healthcare Distributor	RIEMSER	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Country of Destination	GERMANIA	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Product	OUTER 21 PZ GELCLAIR 15 ML	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Code Finished Product	OHEL70020315	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Finished Product Batch #	106111	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Batch size	1.659 pz (3pz for HELSINN)	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Bulk Batch #	07411	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Bulk Size	2.735 kg	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Expiry Date	2024/02	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Date of Bulk Manufacturing	15-03-21	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Date of Primary packaging	Start: 16/04/2021 End: 16/04/2021	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Date of Secondary packaging	16/04/2021	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Deviation/NC	<input checked="" type="checkbox"/> NO <input type="checkbox"/> Yes Notes: Doc. n°: Closure Date:	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Bulk CoA Registration N°	21/02131-1	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes
Finished Product CoA Registration N°	21/03049-1	<input type="checkbox"/> NO <input checked="" type="checkbox"/> Yes

	Name	Date	Signature
Issued by (Biokosmes)	Claudia Bolis	22/04/2021	
Verified by (Biokosmes)	Elena Rigamonti	22/04/2021	
Checked by (HHC MOD QA)	BARBARA PATERNI	26/04/2021	

Customer HELSINN HEALTHCARE S.A.			
Product	Item	Description	
	0HEL70020315	RIEMSER - OUTER 21PZ GELCLAIR 15ml	
Lot	106111		
No of Registration	21/02954	Number of Analysis 21/03049-1	Starting date of Analysis 16/04/2021
			Ending date of Analysis 22/04/2021

Control parameters Method of analysis	Rif.	Measur. unit	Specification Ref. T.S. ed. 0,0 of 24/03/2020	Result
cq16 - IN COMPLIANCE WITH REFERENCE SAMPLE MET.CQ/CMC		N/A	IN COMPLIANCE	IN COMPLIANCE
cq27 - IN COMPLIANCE WITH BILL OF MATERIALS IST.CQ/CPF		N/A	IN COMPLIANCE	IN COMPLIANCE
cq28 - LEAK TEST IST.CQ/CPF		N/A	IN COMPLIANCE	IN COMPLIANCE
cq28 - FINISHED PRODUCT CONTENTS IST.CQ/CPF		N/A	IN COMPLIANCE	IN COMPLIANCE
cq29 - VARIABLE DATA IST.CQ/CPF		N/A	IN COMPLIANCE	IN COMPLIANCE
cq48 - EXPIRY DATE IST.CQ/CPF		N/A	36 MESI (aaaa/mm)	2024/02
cq13 - AEROBIC MESOPHILIC BACTERIA TOTAL COUNT MET.CQ/CTB (Eur. Pharm. 2.6.12)		UFC/ML	< 10	< 10
cq14 - YEAST AND MOULDS TOTAL COUNT MET.CQ/CTF (Eur. Pharm. 2.6.12)		UFC/ML	< 10	< 10
cq44 - PSEUDOMONAS AERUGINOSA MET.CQ/RMS (Eur. Pharm. 2.6.13)		UFC/ML	ABSENT	ABSENT
cq45 - ESCHERICHIA COLI MET.CQ/RMS (Eur. Pharm. 2.6.13)		UFC/ML	ABSENT	ABSENT
cq46 - STAPHYLOCOCCUS AUREUS MET.CQ/RMS (Eur. Pharm. 2.6.13)		UFC/ML	ABSENT	ABSENT
cq47 - CANDIDA ALBICANS MET.CQ/RMS (Eur. Pharm. 2.6.13)		UFC/ML	ABSENT	ABSENT
cq39 - MANUFACTURING DATA BULK Metodo Visivo		N/A	dd-mm-yy	15-03-21

According to the analytical data of the batch and the checks performed at every stage of the manufacturing process, the product is in compliance with the defined specifications.

Date	22 APR 2021	Quality Control Signature		Date	22 APR 2021	Quality Assurance Signature	
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Biokosmes S.r.l. - Socio Unico

Soggetta a Direzione e Coordinamento di Venture Life Group PLC - U.K.

Via dei Livelli, 1 - 23842 Bosisio Parini (LC) - Italy - Tel. +39 031 3581085 Fax + 39 031 3581082

e-mail: biokosmes@biokosmes.it - www.biokosmes.it

Sede Legale: 20122 Milano - Via Besana, 10 - Cap. Soc. 100.000 € int. vers.

R.I. Milano / Codice Fiscale / Partita IVA 01430480135 - R.E.A. Milano 1863413

Customer HELSINN HEALTHCARE S.A.			
Product	Item	Description	
	OHEL4002ED03	HELSINN - GELCLAIR	
Lot	07411		
No of Registration	21/01855	Number of Analsys 21/02131-1	Starting date of Analysis 15/03/2021
		Ending date of Analysis 22/03/2021	

Control parameters Method of analysis	Rif.	Measur. unit	Specification Ref. T.S. ed. 1,0 of 02/11/2010	Result
CQ01 - APPEARANCE MET.CQ/DCA		N/A	OPAQUE GEL	OPAQUE GEL
CQ02 - COLOR MET.CQ/DCC		N/A	FROM WHITE TO PALE YELLOW	WHITE
CQ03 - ODOR MET.CQ/DCO		N/A	CHARACTERISTIC	CHARACTERISTIC
CQ07 - TEMPERATURE Non Applicable/Not Applicable		°C	Low.Lim. 23,0 Upp. Lim. 27,0	23,6
CQ04 - pH MET.CQ/DCP		pH	Low.Lim. 6,50 Upp. Lim. 6,50	6,37
CQ05 - VISCOSITY MET.CQ/DCV Brookfield LV DVII+ S62 - 3 Rpm		mPas	Low.Lim. 4.500 Upp. Lim. 7.500	7.009
CQ05 - DENSITY MET.CQ/DCD		g/ml	Low.Lim. 1,013 Upp. Lim. 1,073	1,048
CQ16 - IN COMPLIANCE WITH REFERENCE SAMPLE MET.CQ/CMC		N/A	IN COMPLIANCE	IN COMPLIANCE
CQ13 - AEROBIC MESOPHILIC BACTERIA TOTAL COUNT MET.CQ/CTB (Eur. Pharm. 2.6.2)		UFC/ml	< 10	< 10
CQ14 - YEAST AND MOULDS TOTAL COUNT MET.CQ/CTF (Eur. Pharm. 2.6.12)		UFC/ml	< 10	< 10
CQ44 - PSEUDOMONAS AERUGINOSA MET.CQ/RMS (Eur. Pharm. 2.5.13)		UFC/ml	ABSENT	ABSENT
CQ45 - ESCHERICHIA COLI MET.CQ/RMS (Eur. Pharm. 2.3.13)		UFC/ml	ABSENT	ABSENT
CQ46 - STAPHYLOCOCCUS AUREUS MET.CQ/RMS (Eur. Pharm. 2.6.12)		UFC/ml	ABSENT	ABSENT
CQ47 - CANDIDA ALBICANS MET.CQ/RMS (Eur. Pharm. 2.6.13)		UFC/ml	ABSENT	ABSENT
CQ38 - PSEUDOMONACEAE MICROORGANISMS RESEARCH I		N/A	ABSENT	ABSENT

According to the analytical data of the batch and the checks performed at every stage of the manufacturing process, the product is in compliance with the defined specifications

Date	22 APR 2021	Quality Control Signature		Date	22 APR 2021	Quality Assurance Signature	
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Customer
HELSINN HEALTHCARE S.A.

Product	Item	Description
	OHEL4002ED03	HELSINN - GELCLAIR
Lot	07411	

No of Registration	21/01855	Number of Analysis	21/02131-1	Starting date of Analysis	15/03/2021	Ending date of Analysis	22/03/2021
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Control parameters Method of analysis	Rif.	Measur. unit	Specification Ref. T.S. ed. 1,0 of 02/11/2010	Result
METCO/RMS (Eur. Pharm. 2 6 13)				

According to the analytical data of the batch and the checks performed at every stage of the manufacturing process, the product is in compliance with the defined specifications.

Date	22 APR 2021	Quality Control Signature		Date	22 APR 2021	Quality Assurance Signature	
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