

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	☐ YES (n.°.....)	☒ NO
Conformity of Supplier CoAs	☒ YES	☐ NO
Conformity Batch Record Abstract	☒ YES	☐ 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

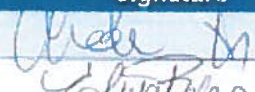
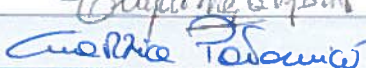
HELSINN HEALTHCARE S.A.

Via Pian Scairolo 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	☐ NO ☒ Yes
Biokosmes Order Confirmation #	20/00833	☐ NO ☒ Yes
Helsinn Healthcare Distributor	RIEMSER	☐ NO ☒ Yes
Country of Destination	GERMANIA	☐ NO ☒ Yes
Product	OUTER 21 PZ GELCLAIR 15 ML	☐ NO ☒ Yes
Code Finished Product	0HEL70020315	☐ NO ☒ Yes
Finished Product Batch #	106111	☐ NO ☒ Yes
Batch size	1.659 pz (3pz for HELSINN)	☐ NO ☒ Yes
Bulk Batch #	07411	☐ NO ☒ Yes
Bulk Size	2.735 kg	☐ NO ☒ Yes
Expiry Date	2024/02	☐ NO ☒ Yes
Date of Bulk Manufacturing	15-03-21	☐ NO ☒ Yes
Date of Primary packaging	Start: 16/04/2021 End: 16/04/2021	☐ NO ☒ Yes
Date of Secondary packaging	16/04/2021	☐ NO ☒ Yes
Deviation/NC	☒ NO ☐ Yes Notes: Doc. n°: Closure Date:	☐ NO ☒ Yes
Bulk CoA Registration N°	21/02131-1	☐ NO ☒ Yes
Finished Product CoA Registration N°	21/03049-1	☐ NO ☒ 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)	MARIA PATERLINI	26/04/2021	

MOD AQ/COA Ed.03 del 29/01/2018

CERTIFICATE OF ANALYSIS

22 Aprile 2021

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Customer

HELSINN HEALTHCARE S.A.

Product

Item

0HEL70020315

Description

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/CNC		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. 2.8.13)		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

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

MOD.AQ/COA Ed.03 del 29/01/2018

CERTIFICATE OF ANALYSIS

22 Aprile 2021

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Customer

HELSINN HEALTHCARE S.A.

Product

Item

0HEL4002ED03

Description

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

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
CQ37 - 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
CQ06 - 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. 2.6.13)	UFC/ml	ABSENT	ABSENT
CQ47 - CANDIDA ALBICANS MET.CQ/RMS (Eur. Pharm. 2.6.13)	UFC/ml	ABSENT	ABSENT
CQ38 - PSEUDOMONACEAE MICROORGANISMS RESEARCH	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

Biokosmes S.r.l. - Socio Unico

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CERTIFICATE OF ANALYSIS

Pag. 2/2

HELINN HEALTHCARE S.A.

Item

0HEL4002ED03

Description

HELSINN - GELCLAIR

Lot

07411

No of Registration

21/01855

Number of Analyses

21/02131-1

Starting date of Analysis

15/03/2021

Ending date of Analysis

22/03/2021

Control parameters
Method of analysis

Ref

Measur.
unit

Specification
Ref. T.S. ed. 1.0 of 02/11/2010

Result

METCORMS (Eur. Pharm. 2613)

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.

Data

Quality Control

Signature

27 APR 2021

Date _____

22 APR 2021

Quality Assurance

Signature _____

Biokosmes S.r.l. – Socio Unico

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