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

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

BATCH RELEASE

European Representative: N.A.

Product:

Product	Gelclair 180 ml
Code	0HEL70020306
Batch Number	103181
Number of Units	5.121 (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: Sappio Paternicò ..... *Lugano (CH), Date:* 11/05/2021 .....

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:* ...11/05/2021...

HELSINN HEALTHCARE S.A.

Via Pian Scairolo 9 – Pambio Noranco – 6915 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	GELCLAIR 180 ML	☐ NO ☑Yes
Code Finished Product	0HEL70020306	☐ NO ☑Yes
Finished Product Batch #	103181	☐ NO ☑Yes
Batch size	5.121 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: 13/04/2021* *End: 13/04/2021*	☐ NO ☑Yes
Date of Secondary packaging	20/04/2021	☐ 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°	21/03157-1	☐ NO ☑Yes

	Name	Date	Signature
Issued by *(Biokosmes)*	*Claudia Bolis*	*28/04/2021*	
Verified by *(Biokosmes)*	*Anna Romeo*	*28/04/2021*	
Checked by *(HHC MDD QA)*	MARZIA PATERNICÒ	11/05/2021	Marzia Paternicò