

DECLARATION OF CONFORMITY

IN ACCORDANCE WITH COUNCIL DIRECTIVE 93/42/EEC as amended by Directive 2007/47/EC

Manufacturer:**HELSINN HEALTHCARE SA**

via Pian Scaiolo 9 – Pazzallo – 6912 Lugano – CH

European Representative:

N.A.

Product: Gelclair® Concentrated Oral Gel**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 980; 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

EC Certificate(s):

G2 14 10 70849 005; exp. 2019-11-17

We herewith 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.
Supporting documentation is retained under the premises of the manufacturer.

The present Declaration of Conformity is valid for all lots manufactured from issue date to 2019-11-17.

HELSINN HEALTHCARE SAGiuseppina Fusetti, M. Chem. Pharm.
Senior Manager, Corporate Regulatory AffairsPazzallo - Lugano, 31st May 2017