

DECLARATION OF CONFORMITY

Product identification

Product name: Sterile Sodium Hyaluronate for intra-articular use.

Brand name: PROMOVIA, VISCOIAL.

Model: PROMOVIA pre-filled syringe of 4 ml, with 2% of medium chain HA (80 mg).

Classification: Class III, rule 8, Annex IX of MDD 93/42/EEC

Route of certification: Annex II section 3 and Annex 2 Section 4

Manufacturer

Name: INNATE s.r.l.

Address: Viale Industria, 11-13 15067 Novi Ligure.

Telephone number: +3901432645

Mail: info@innate.it

Country: ITALY.

Means of conformity

INNATE s.r.l. Viale Industria, 11-13 15067 Novi Ligure (ITALY) declares that the product listed complies with Directive 93/42/CEE dated June, 14th 1993 modified by the Directive 2007/47/CE dated September, 5th 2007 and book No. V bis from the public health code (article R 665-1 et al., if applicable). This declaration is based on the full quality assurance system certification (certificate N°1984-MDD-18-506 and 1984-MDD-18-507) delivered by KIWA (Notified body number 1984), Istanbul Tuzla organize Sanayi Bolgesi 9. Cad. No 15 Tepeören Mevkii 34959, Tepeören Osb/Tuzla/Istanbul

Harmonized standards

EN 556-1:2001/AC:2006, EN 15223-1:2016

UNI EN ISO 10993-1:2021, ISO 14630 :2012,

UNI EN ISO 11737-1:2018, EN ISO 11737-2:2021, EN ISO 13485:2016, EN ISO 14155:2020, EN ISO 14971:2019, EN ISO 14644-1:2015, EN ISO 14644-2:2015.

Novi Ligure, 30/07/2022

The General Manager



Federico Panzieri