

DECLARATION OF CONFORMITY

Product name: Sodium Hyaluronate for intra-articular use.

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

Brand names:

- VISCOS

Models:

Product Description	Trade Name	Code
Sodium Hyaluronate for intra-articular use	- VISCOS 40 M	1303
Sodium Hyaluronate for intra-articular use	- VISCOS 60 M	1315
Sodium Hyaluronate for intra-articular use	- VISCOS 80 M	1321
Sodium Hyaluronate for intra-articular use	- VISCOS 40 H	1300
Sodium Hyaluronate for intra-articular use	- VISCOS 60 H	1312
Sodium Hyaluronate for intra-articular use)	- VISCOS 80 H	1318

Manufacturer

Name: The Wave Innovation Group srl

Address: Via Monsignor Luigi Bellotti, 16 - 37139 Verona ITALY.

Country: ITALY.

Means of conformity

The Wave Innovation Group srls hereby declares that the products listed comply with Directive 93/42/CEE dated June 14th 1993 modified by the Directive 2007/47/CE dated September, 5th 2007, and with the Article 120-3 of Regulation (EU) 2017/745 of 5 April 2017 as amended. This conformity assessment route is based on the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance system - Certificate n° QCT-0159-20 released on 2020.07.20. revised on 2020.09.10, expiry date: 2024.05.26), including point II.4 (design examination- Certificate n° EPG-0306-20 released on 2020.07.20. revised on 2020.09.10, expiry date: 2024.05.26), certified by ISTITUTO SUPERIORE DI SANITA' (Notified Body number 0373), Viale Regina Elena, 299 – 00161 ROMA (ITALY).

Harmonized standards applied

EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020, EN ISO 14630:2012, IEC 62366-1:2015, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN 556-1:2001, EN ISO 11138-3:2017, EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:2021, EN ISO 11737-2:2020, EN ISO 17665-1:2006, EN ISO 14937:2009, EN ISO 11140-1:2014, EN ISO 11140-3:2009, EN 285:2015+A1:2021, EN ISO 11607-1:2020, EN ISO 11607-1:2020/A11:2022, EN ISO 11607-2:2020, EN ISO 11607-2:2020/A11:2022, EN ISO 15223-1:2021, EN ISO 10993-1:2020, EN ISO 10993-2:2006, EN ISO 10993-3:2014, EN ISO 10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-9:2021, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-13:2010, EN ISO 10993-14:2009, EN ISO 10993-15:2009, EN ISO 10993-16:2017, EN ISO 10993-17:2009, EN ISO 10993-18:2020, ISO/TS 10993-19:2020, ISO 10993-20:2006, EN ISO 10993-23:2021, EN ISO 14155:2020, EN ISO 20417:2021, CEN ISO/TR 20416:2020, ASTM F1980-16, ASTM D4169-16.

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