Lodi, 01 Aug 2025

EU DECLARATION OF CONFORMITY

The undersigned company **IBSA Farmaceutici Italia srl**, located at Via Martiri di Cefalonia, 2 – 26900 LODI (ITALY), registered on EUDAMED with the following registration number:

SRN: IT-MF-000008111

Manufacturer of the following medical device:

Product name: VISCO-SUPPLETIVE JOINT DEVICE

Trade name and presentation: SINOVIAL - 0.8% - 16 mg/2 ml Hyaluronic Acid Sodium Salt –kit of 1 syringe

Batch nr: E01605 *Quantity:* 3.081

Manufacturing Date: 2025/02 *Expiry Date:* 2028/02

Certificate of analysis nr: 170000052249

Basic UDI-DI: 803363895IA0034V

Risk class: The medical device has been classified as Class III, according to the rules 8 of the Annex VIII of the Regulation EU 2017/745

Sterile: YES

Device with a measuring function: NO

Device intended for clinical investigations: NO

Common Specifications used:

Name and Identification number of Notified Body: Eurofins Product Testing Italy S.r.l. ON0477

Conformity assessment procedure performed: pursuant to Article 52 point 3 that follows the dictates of Annex IX "CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION"

EC certificate N°: EU QUALITY MANAGEMENT SYSTEM CERTIFICATE N° EPT 0477.MDR.22/4840
EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE N° EPT 0477.MDR.22/4839

DECLARES

That the above information is authentic, accurate and the above-mentioned Medical Device fulfils all the provisions laid down and is in conformity with the REGULATION (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

This EU declaration of conformity is hereby issued under the sole responsibility of the manufacturer of medical device. The Manufacturer set up a systematic procedure for evaluating the acquired experience in the use of medical devices in the phase following the production and for foreseeing an adequate system to be applied for corrective actions when needed, in case of incidents according to the provisions laid down in accordance with the Chapter VII, of the above-mentioned REGULATION, as amended.

The Manufacturer commits to filing and to making available to the competent Authorities the technical documentation described in the Annex II of REGULATION (EU) 2017/745, for a period of at least fifteen years from the date of production of the last batch.

IBSA Farmaceutici Italia S.r.l

[Cinzia Pagliari, *PRRC*]

Lodi, 01 Aug 2025

CERTIFICATE OF CONFORMITY

The undersigned company IBSA Farmaceutici Italia srl, located at Via Martiri di Cefalonia, 2 – 26900 LODI (ITALY), registered on EUDAMED with the following registration number:

SRN: IT-MF-000008111

in conformity with Regulation (EU) 2017/745 Art. 22.1 a), as amended, combines the following Medical Devices in order to place them on the market as a System:

- VISCO-SUPPLETIVE JOINT DEVICE, in all presentations, bears CE Mark 0477 and is manufactured by IBSA Farmaceutici Italia srl
- Needle 21 G x 1 ½" bears CE Mark 0197 and is manufactured by TERUMO Europe N.V

IBSA combines the listed Devices in compliance with their Intended Purpose and within the Limits of Use specified by the Manufacturer.

These SYSTEM has the following specifications:

Product description: SINOVIAL - 0.8% - 16 mg/2 ml Hyaluronic Acid Sodium Salt –kit of 1 syringe together with needle 21 G x 1 ½"

Basic UDI-DI: 803363895IAK0036B

Batch nr: E01605

Certificate of Analysis nr: 170000055875

Quantity: 3.081

Manufacturing Date: 2025/02

Expiry date: 2028/02

Furthermore, in conformity with Regulation (EU) 2017/745 Art. 22.2, IBSA Farmaceutici Italia

DECLARES THAT

- it's been verified the mutual compatibility of the devices.
- it's been packaged the system and supplied relevant information to users.
- the activity of combining devices was subject to appropriate methods of internal monitoring, verification, and validation.

IBSA Farmaceutici Italia S.r.l

Cinzia Pagliari

[Cinzia Pagliari, *PRRC*]