Lodi, 13 May 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: Sodium hyaluronate 2.4% and sodium chondroitin 1.6% - Visco-suppletive joint device

Trade name and presentation: SINOGEL 2,4% 72 mg (HA) + 1,6% 48 mg (CS)/3 ml

Batch nr: E01938 *Quantity:* 1.160

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

Certificate of analysis nr: 170000052341

Basic UDI-DI: 803363895IA0024T

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.22/4844
EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE N° EPT 0477.MDR.22/4843

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, 13 May 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:

- SINOGEL 2,4% 72 mg (HA) + 1,6% 48 mg (CS)/3 ml 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.

This SYSTEM has the following specifications:

Product description: SINOGEL 2,4% 72 mg (HA) + 1,6% 48 mg (CS)/3 ml with a needle 21 G x 1 ½"

Basic UDI-DI: 803363895IAK00269

Batch nr: E01938

Certificate of Analysis nr: 170000052341

Quantity: 1.160

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, *PRRC*]

IBSA Farmaceutici Italia S.r.l.

CERTIFICATE OF ANALYSIS Nº: 170000052341

SINOGEL HA 2.4% + CSF 1.6% 1 syr CZ

Product Code:	6000003190	**Expiry date:**	2028/02
Batch number:	E01938	**Manufacturing date:**	2025/02
		Quantity:	1.160 PC

Strength/Potency: Hyaluronic Acid Sodium Salt Solution 2.4% + Condroitin Sulphate Salt Soluttion 1.6 %
Destination Country: Czech Republic
Package size and type: 1 prefilled syringe solution / Pack
Dosage Form: Syringes

TESTS	SPECIFICATIONS	UM	RESULTS	ANALYTICAL METHOD
Appearance	Syringes containing a transparent, clear and colorless homogeneous gel		Complies	MAN.PF/09.17.74
Extractable volume	≥ 3,0	ml	3,1	
pH	6,5 - 7,5		6,8	
Dynamic viscosity	1750 - 3250	mPa.s	2535	
Osmolality	250 - 450	mOsmol/kg	313	
Na Hyaluronate and Na Chondroitin Ident.	Presence of two peaks corresponding to Sodium Hyaluronate and Sodium Chondroitin		Complies	
Na Hyaluronate and Na Chondroitin assay	90,0 - 110,0	% s.v.	96,9	
Bacterial endotoxins	≤ 3,8	IU/ml	< 0,4	MAN.PF/10.17.65
Sterility	Sterile		Sterile	
Packaging control	Complies		Complies	MAN.PF/11.17.01

Daniela Attili
Quality Control
May 09, 2025 17:19:07 APPROVED
IBSA Farmaceutici Italia Srl

Print date 14.05.2025

This document has been signed and generated electronically, by an electronic system, validated in full compliance with current GMP.

Headquarters and Marketing Operations
Via Martiri di Cefalonia, 2, 26900, Lodi, Italy
Telephone +3903716171, Fax +390371617244

Manufacturing and Quality Control
Via Martiri di Cefalonia 2, 26900 Lodi, Italy
Telephone:+3903716171
N. Manufacturing Auth.: AM-190/2024

Lodi, 13 May 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: D13823 *Quantity:* 3.383

Manufacturing Date: 2024/11 *Expiry Date:* 2027/11

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*]

Sede legale e Stabilimento
Via Martiri di Cefalonia, 2 - 26900 LODI
Tel. +39 0371 6171 - Fax +39 0371 617244

Stabilimento di Cassina de' Pecchi
S.S. 11, Padana Superiore km 160 - 20051 Cassina de' Pecchi (MI)
Tel. +39 0371 617292 Fax +39 0371 617368

Sede di Roma
Via del Tritone, 169 - 00187 ROMA
Tel. +39 06 94378600 Fax +39 06 94378699

Sede amministrativa
Via della Filanda, 30 - 26900 LODI
Tel. +39 0371 617292 Fax +39 0371 617368

Lodi, 13 May 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: D13823

Certificate of Analysis nr: 170000052249

Quantity: 3.383

Manufacturing Date: 2024/11

Expiry date: 2027/11

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, *PRRC*]

IBSA Farmaceutici Italia S.r.l.

CERTIFICATE OF ANALYSIS Nº: 170000052249

SINOVIAL 16 mg /2ml 1 f.s.+needle 21G CZ

Product Code: 6000001296
Batch number: D13823

Expiry date: 2027/11
Manufacturing date: 2024/11
Quantity: 3.383 PC

Destination Country: Czech Republic
Marketing Auth. Holder: IBSA FARMACEUTICI ITALIA

TESTS	SPECIFICATIONS	UM	RESULTS	ANALYTICAL METHOD
Appearance	Syringes containing a transparent, clear and colorless gel		Complies	MAN.PF/09.17.01
Extractable volume	≥ 2,0	ml	2,0	
pH	6,5 - 7,5		7,1	
Dynamic viscosity	≥ 50	mPa.s	241	
Osmolality	250 - 350	mOsmol/kg	298	
Sodium Hyaluronate Identification (HPLC)	The principal peak in the test solution chromatogram corresponds for RT and shape the principal peak in the reference solution chromatogram		Complies	
Sodium Hyaluronate assay	90,0 - 110,0	% s.v.	109,5	
Bacterial endotoxins	≤ 8,75	IU/ml	< 0,45	MAN.PF/10.17.05
Sterility	Sterile		Sterile	
Packaging control	Complies		Complies	MAN.PF/11.17.01

Daniela Attili
Quality Control
May 09, 2025 07:06:40 APPROVED
IBSA Farmaceutici Italia Srl

Print date 14.05.2025

This document has been signed and generated electronically, by an electronic system, validated in full compliance with current GMP.

Headquarters and Marketing Operations
Via Martiri di Cefalonia, 2, 26900, Lodi, Italy
Telephone +3903716171, Fax +390371617244

Manufacturing and Quality Control
Via Martiri di Cefalonia 2, 26900 Lodi, Italy
Telephone:+3903716171
N. Manufacturing Auth.: AM-190/2024