Lodi, 30/01/2019

DECLARATION OF CE CONFORMITY

Declaration of CE Conformity of the medical device "HYALURONIC ACID SODIUM SALT, VISCOSUPPLETIVE JOINT DEVICE" in the following presentations:

Brandnames	Percentage of hyaluronic acid						
	0,8%		1,0%	1,6%		2,0%	
Volume	1 ml	2 ml	2 ml	2 ml		2,5ml	
Sinovial	X (Mini)	X	X	X (Forte\Fort)	X (Highvisc)	X (One)	X (Once)
Intragel	X (Mini)	X	X	X		X (One)	X (Once)
Yaral	X (Mini)	X	X	X (Forte)		X (One)	X (Once)
Gony Alert MD	X (Mini)	X	X	X (Forte)		X (One)	X (Once)

Pre-filled syringe containing a buffered physiological solution of hyaluronic acid for intraarticular use, manufactured by IBSA Farmaceutici Italia srl

The undersigned company **IBSA Farmaceutici Italia srl**, located at Via Martiri di Cefalonia, 2 - 26900 LODI (ITALY), Manufacturer of the medical device *HYALURONIC ACID SODIUM SALT, VISCOSUPPLETIVE JOINT DEVICE, pre-filled syringe containing a buffered physiological solution of hyaluronic acid for intraarticular use,* after ensuring its conformity to Directive 93/42/EEC, as amended by Directive 2007/47/EC, according to Annex II (4) with EC design - examination certificate n. EGP-0097-18 of 26.04.2018, together with the procedure relevant to the EC declaration of conformity according to Annex II excluding (4) - Full Quality assurance system certificate n. QCT-0043-17 add. n. 01-18 of 26.04.2018, both issued by Istituto Superiore di Sanità (0373),

DECLARES

that the above mentioned Medical Device fulfils all the provisions laid down in Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC.

Therefore **IBSA Farmaceutici Italia srl** assures, under its own responsibility, the following:

- the above mentioned Medical Device complies with the Essential Requirements listed in Directive 93/42/EEC, as amended by Directive 2007/47/EC;
- the above Medical Device falls in **Class III**, as per classification rule n. 8 in the Annex IX, paragraph 2.4, of the Directive as amended;

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Registro delle Imprese di Lodi C.C.I.A.A.: 1452594 Cap Soc.: € 8.000.000 i.v.

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- the above mentioned Medical Device is placed on the market STERILE;
- the above mentioned Medical Device IS NOT A DEVICE WITH A MEASURING FUNCTION;
- the above mentioned Medical Device underwent a risks evaluation based on the standard UNI CEI EN ISO 14971;
- the above mentioned Medical Device IS NOT A DEVICE INTENDED FOR CLINICAL INVESTIGATIONS;
- 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 the Annex V, paragraph 3 of the above mentioned Directive as amended;
- the Manufacturer commits to filing and to making available to the competent Authorities the technical documentation described in the Annex II of the Directive 93/42/EEC as amended, for a period of at least fifteen years from the date of production of the last batch.
- The undersigned Company also declares that the medical device can also be marketed with the following brand-names:
  - INTRAGEL
  - YARAL
  - SINOVIAL
  - GONY ALERT MD

IBSA Farmaceutici Italia srl

Dr. Luca Crippa
Legal Representative