Lodi, 04/02/2019

DECLARATION OF CE CONFORMITY

Declaration of CE Conformity of the medical device HILOW, VISCO-SUPPLETIVE JOINT DEVICE, in the following presentations:

- ***3.2%- 16 mg (H-HA) + 16 mg (L-HA)/1 ml;***
- ***3.2%- 32 mg (H-HA) + 32 mg (L-HA)/2 ml,***

Pre-filled syringe containing a buffered physiological solution of hyaluronic acid for intra-articular use, manufactured by the Company 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 ***HiLow, VISCO-SUPPLETIVE JOINT DEVICE,*** *pre-filled syringe containing a buffered physiological solution of hyaluronic acid for intra-articular use,* after ensuring its conformity to Directive 93/42/EEC as amended according to Annex II (4) with EC design-examination certificate n. EPG-0096-18 dated 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 addendum n° 01-18 dated 26.04.2018, issued by the Notified Body Istituto Superiore di Sanità (0373),

DECLARES

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

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;
- 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;
- the above mentioned Medical Device is placed on the market STERILE;
- the above mentioned Medical Device IS NOT A DEVICE WITH A MEASURING FUNCTION;

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- 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 Directive 93/42/EEC as amended, for a period of at least fifteen years from the date of production of the last batch.
- the above mentioned Medical Device can be placed on the market with the following brand names:
  - SINOVIAL HL
  - INTRAGEL HL
  - YARAL HL

IBSA Farmaceutici Italia Srl

Dr. Luca Crippa
Legal Representative