DECLARATION OF COMPLIANCE

Provisions laid down in ANNEX I of Legislative Decree no. 46/97 and amended with the Legislative Decree no. 37/10 of Italian Law - Implementation of Directive 2007/47/EEC, correction of Directive 93/42/EEC Annex VII of governed the law above

MEDICAL DEVICE NAME

HA2% - 40mg/2ml:

☒ JOYFLEX 2% Batch 911807 Exp. 11/2022

☐ VISCOMEN 2%

☐ CONDRONIL IALDUE

☐ JALOFIX 40

☐ SINTIAL 2%

☐ EGANIS ONE 2%

☐ NANOFLEX 2%

☐ VISCOTEC 2%

☐ ADBIOJAL INTRA 2%

☐ LOCTOSPAN

☐ IALFLEX 40

HA2% - 80mg/4ml:

☐ JOYFLEX ONE

☐ IALFLEX 80

☐ RENILAST

Indication: substitute of synovial fluid into joints

Legal Manufacturer ALFAKJN S.r.l.

Alfakjn s.r.l., with registered offices in Piazza Repubblica n. 22-cap 27026 - Garlasco (PV), the manufacturer of the medical device, named:

DECLARES

under its own responsibility that:

- The device complies with the requirements of Directive 2007/47 / EEC, corrective Directive 93/42 / EEC implemented in Italy by Legislative Decree no. 46/97 and amended with the Legislative Decree no. 37/10 of Italian Law and the Technical File FT.CE.02_OBL;
- The above device is a Class III medical device as required by rule 8 (invasive surgical devices for long-term use entirely absorbed) of Annex IX (classification criteria) Chapter III (CLASSIFICATION), in reference to 'Article 11 of the Legislative Decree no. as amended and integrations;

- The manufacturer agrees to maintain and make available to the Authority's Technical File Product (FT.CE.02_OBL), as specified in Annex II, including section 4, of Directive 2007/47 / EEC, Directive 93/42 corrective 2007/47 / EEC of reference for a period of at least 15 years after the last entry on the market of the last lot or serial number of the device indicated.
- The medical device HA based on hyaluronic acid is a replacement of synovial fluid in the joints affected by degenerative arthropathy or mechanics, which causes pain or reduced mobility.
- The conformity assessment route follow is the annex II of Directive 2007/47 / EEC, Directive corrective of 93/42 EEC
- The device has certificate of the notified body n ° 1984 - Kiwa Certification Services Inc. ITOSB 9. Cadde No:15 Tepeoren Tuzla Istanbul Turkey. Phone: +90 2165932575; Fax: +90 2165932574. www.kiwa.com.tr

Applied Standards

- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 10993-1:2009/AC:2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 10993 (series) - Biological evaluation of medical devices
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO14971:2007, Corrected version 2007-10-01)
- EN ISO 15223-1:2016 (Corrected version 2017-03) Symbols for use in the labelling of medical devices
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- EN ISO 14155:2011/AC:2011 Clinical investigation of medical devices for human subjects - Good clinical practice
- EN ISO 11737-1:2006/AC:2009 Sterilization of medical devices - Microbiological methods Part 1: Determination of a population of microorganisms on products
- EN ISO 11737-2:2009, Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EN 62366:2008 Medical devices - Application of usability engineering to medical devices
- EN 556-1:2001/AC:2006 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
- EN ISO 11138-2:2009, Sterilization of health care products. Biological indicators. Biological indicators for ethylene oxide sterilization processes
- EN ISO 14630:2009, Non-active surgical implants -- General requirements
- ISO 14644-1:2015, Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
- ISO 14644-2:2015 Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.

Date: 20.12.2019

Alfakjn S.r.l.
CEO
Dott. Alessio Ferrari