# EC DECLARATION of CONFORMITY

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| Manufacturer's name: | Fidia Farmaceutici S.p.A. |
| Manufacturer's address: | Via Ponte della Fabbrica, 3/A<br>35031 Abano Terme (PD) – Italy |
| Name of device: | **HYALUBRIX** |
| Description: | Viscoelastic solution for intra-articular use in pre-filled syringe |
| Intended use: | HYALUBRIX is a temporary synovial fluid replacement to be administered by intra-articular injection. |
| Indications | HYALUBRIX is indicated for the treatment of pain and the improvement of joint functionality in patients affected by degenerative or mechanical arthropathy. |
| Presentation: | Pre-filled syringe containing 30 mg/2 ml solution sterilized by steam, in sealed preformed blister.<br>card board box containing 1 blister<br>card board box containing 3 blisters<br>card board box containing 50 blisters (for Healthcare Facilities only)<br>card board box containing 100 blisters (for Healthcare Facilities only)<br>The codes for each presentation are provided in the following table |

| Trade Name | Description | Presentation | Packaging ( unit / box ) | Code |
|---|---|---|---|---|
| **HYALUBRIX** | Solution 30 mg/2ml | Pre-filled syringe | 1 | EQ47-01-1C |
| | | Pre-filled syringe | 3 | EQ47-01-1D |
| | | Pre-filled syringe | 50 (for Healthcare Facilities only) | EQ47-01-1G |
| | | Pre-filled syringe | 100 (for Healthcare Facilities only) | EQ47-01-1H |

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| Classification (according to Dir. 93/42/EEC subsequent amendments and integrations): | Class III – Rule 8 |
| Technical file reference: | CE file named TF EQ47 |

I, the undersigned, hereby declare, under my sole responsibility, that the medical device specified above conforms with the relevant provisions of Directive 93/42/EEC subsequent amendments and integrations which apply to it.

This declaration is supported by:

- Type examination (Annex III) EC certificate no. 10285 rev. 14 + DC 37240 rev.4, valid until 26/05/2024, issued by LNE/G-MED 0459.;
- Approval of production quality assurance system (Annex V) EC certificate no. 8825 rev. 18 + DC 37150 rev.2, valid until 26/05/2024, issued by LNE/G-MED 0459

Place: Abano Terme (PD)
DoC Issue date: 3rd December, 2021
DoC Expiry date : 26th May, 2024

Enrico Pozzi
Qualified Person

fidia

# LIST OF APPLICABLE NORMS AND STANDARDS

| No | Category | REFERENCE | DESCRIPTION |
|---|---|---|---|
| 1 | **System / General** | Directive 93/42/EEC (as amended) | Medical Devices Directive |
| | | ISO 9001:2015 | Quality Systems |
| | | EN ISO 13485:2016 | Quality Systems for Medical Devices |
| | | EN ISO 14971:2019 | Application of Risk Management to Medical Device |
| | | ISO/TR 24971:2020 | Medical devices — Guidance on the application of ISO 14971 |
| | | Reg 1907/2006 | REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| 2 | **Manufacturing** | COMMISSION DIRECTIVE 2003/94/EC (2003) | Volume 4 - Medicinal Products for Human and Veterinary Use : Good Manufacturing Practice |
| | | 21 CFR 820 (2011) | Medical Devices, Current Good Manufacturing Practice - Quality System Regulation |
| | | European Pharmacopoeia current edition | |
| | | United States Pharmacopoeia current edition | |
| | | ISO 14644-1:2015 | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness |
| 3 | **Sterilization** | EN 556 – 1: 2001/ AC :2006 | Requirements for medical devices to be designated "STERILE". Part 1: Requirements for terminally sterilized medical devices" |
| | | EN ISO 17665-1:2006 | Sterilization of medical devices – validation and routine control of sterilization by moist heat. |
| | | ISO 11138-1:2017 | Sterilization of health care products - Biological indicators - Part 1: General requirements |
| | | EN ISO 11138-3:2017 | Sterilization of health care products -- Biological indicators -- Part 3: Biological indicators for moist heat sterilization processes |
| | | EN ISO 11737-1:2018 | Sterilization of medical devices. Microbiological methods. Determination of the population of microorganisms on products |
| | | EN ISO 14161:2009 | Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results |
| 4 | **Packaging** | EN ISO 11607-1:2019 | Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems |

| No | Category | REFERENCE | DESCRIPTION |
|---|---|---|---|
| | | EN ISO 11607-2:2019 | Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes |
| | | ISO 80369-7:2016 | Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic application. Supersedes ISO 594-1:1986 and ISO 594-2:1998 |
| | | ISO 80369-20:2015 | Small-bore connectors for liquids and gases in healthcare applications -- Part 20: Common test methods |
| **5** | **Stability** | ICH Q1A(R2) | Stability Testing of New Drug Substances and Products |
| **6** | **Biological Evaluation** | EN ISO 10993-1:2020 | Biological evaluation of medical devices – Evaluation and testing. |
| | | EN ISO 10993-2:2006 | Biological evaluation of medical devices. Part 2: Animal Welfare requirements |
| | | EN ISO 10993-3:2014 | Biological evaluation of medical devices – Tests for genotoxicity, carcinogenicity and reproductive toxicity |
| | | EN ISO 10993-5:2009 | Biological evaluation of medical devices – Tests for cytotoxicity, in vitro methods. |
| | | EN ISO 10993-6:2016 | Biological evaluation of medical devices – Tests for local effects after implantation. |
| | | ISO 10993-9:2019 | Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products |
| | | EN ISO 10993-10:2013 | Biological evaluation of medical devices – Tests for irritation and sensitisation. |
| | | EN ISO 10993-11:2018 | Biological evaluation of medical devices. Tests for systemic toxicity |
| | | EN ISO 10993-12:2021 | Biological evaluation of medical devices. Sample preparation and reference materials |
| | | EN ISO 10993-16:2017 | Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables |
| | | EN ISO 10993-17:2009 | Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances |
| | | EN ISO 10993–18:2020 | Biological evaluation of medical devices – Part 18: Chemical characterization of materials |
| | | ISO 10993-23:2021 | Biological evaluation of medical devices – Part 23: Tests for irritation |
| | | ICH M7 | Assessment and control of DNA reactive (mutagenic) impurities in pharmaceuticals to limit potential carcinogenic risk |
| **7** | **Clinical evaluation** | EN ISO 14155:2011 | Clinical investigation of medical devices for human subjects — Good clinical practice |
| | | MEDDEV 2.7/1 rev 4 | Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC |
| **8** | **Labelling** | EN ISO 15223-1:2016 | Graphical symbols for use in the labelling of medical devices |
| | | EN 1041:2008 | Information supplied by the manufacturer of medical |

| No | Category | REFERENCE | DESCRIPTION |
|---|---|---|---|
| | | +A1:2013 | devices |
| 9 | Post Marketing | MEDDEV 2.7/3 rev.3 | Clinical investigations: serious adverse event reporting - SAE reporting form |
| | | MEDDEV 2.12/2 rev 2 | Post Market Clinical Follow-up |
| 10 | Usability | IEC 62366-1:2015 | Medical devices Application of usability engineering to medical devices |