EU DECLARATION OF CONFORMITY

The undersigned Qualified Person of FARMIGEA S.p.A., Via G.B. Oliva 6/8, Italy, hereby certifies that the medical devices sold under the trade name:

Name of the product: LissaFid, 5 mini-containers of 0,3 ml and 5 disposable dispensers

Code: 388

Batch: _____/_____

No. of pieces___/__ (___/__ of which for retained sample archive), is classified in Class IIb according to Rule 21 of Annex VIII of MDR 745/17, Chapter III, par. 7.8. It is used to stain the damaged epithelial cells of the ocular surface that have lost the ability to produce mucus properly and to stain the degenerated mucus after the diagnosis of ocular surface diseases including dry eye syndrome.

The disposable dispensers contained in the product are considered accessories classified in class I sterile according to Rule 1 of Annex VIII of MDR 745/17, Chapter III, par. 4.1.

Farmigea S.p.A., as legal Manufacturer of the product in object, declares the following:

- The SRN code of the Manufacturer is IT-MF-000018521.
- The EU Conformity of Declaration is issued under the sole responsibility of the Manufacturer according to Annex IV of MDR 745/17.
- The Basic UDI DI is 80326688700002SF.
- The ophthalmic solution and dispensers covered by the current declaration are in conformity with Regulation MDR 745/17, as described in the Technical File n. 017, current version.
- The ophthalmic solution and dispensers are sterile in conformity with current GMP requirements, ISO 13408 standards, UNI EN 556 standards and other relevant applicable regulations; their sterility is obtained through validated processes.
- The ophthalmic solution is manufactured in conformity with the Quality Management System according to UNI CEI EN ISO 13485 and following the conformity assessment procedure described in Annex IX Chapter I, III of MDR 745/17, as attested in EC Certificate n. 56317 (current date of issue 20/12/2023, with expiry date 27/11/2028), released by Certiquality - Notified Body n. 0546, Gaetano Giardino Street n. 4, 20123, Milan.
- The dispensers are manufactured in conformity with the Quality Management System according to UNI CEI EN ISO 13485 and following the conformity assessment procedure described in Annex IX Chapter I, III of MDR 745/17, as attested in EC Certificate n. 56318 (current date of issue 28/11/2023, with expiry date 27/11/2028), released by Certiquality - Notified Body n. 0546, Gaetano Giardino Street n. 4, 20123, Milan.
- The technical documentation of the medical device in object is archived at the Manufacturer site and it is available – together with the current declaration of conformity – to the Competent Authorities.
- The Manufacturer has established a suitable procedure for post marketing surveillance and vigilance in conformity to MDR 745/17.
- The undersigned Qualified Person is authorized to issue the current declaration on behalf of the Chief Executive Officer of Farmigea S.p.A.

(rev. 03 of 20/12/2023)

Pisa,
Date: 20/12/2023

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Qualified Person of Farmigea S.p.A.