	STP.24-Annex I	REV. 03
schalcon CLEAR VISION	**Liposome Eye Spray with natural extract, sterile**	Date of issued: 06/10/2021

DECLARATION OF CONFORMITY CE

Ocuvers Spray Lipostamin
Batch number: AA113

The Company Schalcon S.p.A., legally registered and with operational site in Italy, Viale Enrico Ortolani, 195 – 00125 Rome, declares under its responsibility that:

1. The above-mentioned device meets the provision of the Medical Device Directive 93/42/CEE and following (Annex I – Essential Requirements) and the provisions of the Annex II issued by the Notified Body 0477 Eurofins Product Testing Srl;
2. The above-mentioned device is Class IIb classified, in accordance with the Rule 15, Annex IX of the MDD 93/42/EEC and following modifications.
3. All documentation concerning such a device is retained in the Technical File STP.24 and stored for a period of at least 10 years from the last date of the product manufacture.
4. All the development and manufacture steps of the above-mentioned device fulfill the requirements of the Company Quality Management System, as required in Annex II of the MDD 93/42/EEC and following modifications.
5. Such a Quality Management System conforms to the requirements as specified in the Annex II of the MDD 93/42.
6. The Company Schalcon S.p.A. has notified to the Competent Authorities that the device is currently commercialized, on the purpose to guarantee the proper post-market surveillance.
7. The MD is marketed in sterile conditions.

Roma, 17/06/2022

Technical Director
Walter Quattrocchi