| | STP.6 - Annex I | REV. 6 |
|---|---|---|
| schalcon CLEAR VISION | **PEROXIDE SYSTEMS WITH CATALYST FOR CONTACT LENSES** | **Date of issue: 18/01/2020** |

# DECLARATION OF CONFORMITY CE

**Peroxide systems with catalyst for contact lenses**
Linsenpflege OxyStar 100 ml – 300 ml

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 Italy 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.6 and stored for a period of at least 5 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, 18/01/2020

Il Legale Rappresentante
Alberto Sala

Firma