

DECLARATION OF CONFORMITY

1. MANUFACTURER

Esoform S.p.A. Viale del Lavoro, 10 – 45100 Rovigo – Italy

2. PRODUCTS

Contact lens care solutions and drops for eye lubrication as annex list.

3. CONFORMITY ASSESSMENT ROUTE

MDD 93/42 EEC & s.a.s. Annex II

4. CLASSIFICATION

Class IIb in compliance MDD 93/42 EEC & s.a.s .Annex IX Rule 15

5. DECLARATION

We herewith declare under our responsibility that the above mentioned products meet the provisions of the council directive MDD 93/42/EEC & s.a.s for medical devices. All supporting documentation is retained under the premises of the manufacturer and are in conformity with the harmonized standards inforce listed:

ISO 13485; ISO 14971; ISO 15223-1; EN 1041; ISO 14534; ISO 10993- Serie; ISO 11978; ISO 11981; ISO 11986; ISO 13212; ISO 11135; ISO 14937; EN 556; ISO 11737-1-2 ; ISO 11607-1-2; ISO 14644-1-2 ; ISO 13408-2.

We also assure

The application of the Quality Assurance system complies with the requirements of MDD 93/42 EEC & s.a.s. Annex II

The compliance with the essential requirements as MDD 93/42 EEC & s.a.s. Annex I

6. NOTIFIED BODY

ICIM Piazza Don E. Mapelli, 75 20099 Sesto S. Giovanni (MI)



0425

7. EC CERTIFICATE

N°0425-MED-004157-00 of 28 10-2020 expired 31-12-2028

The present declaration is referring to batches manufactured within the period of validity of the above mentioned ICIM EC certificate.

ROVIGO 30 10 2025

Legal representative

Amministratore Delegato
Laura CENCE

Type: Ophthalmic solutions, for the care and conservation of contact lenses

Class: IIb

Multipurpose solutions 104 xx

Model code	Model name
P10402LHVFJ	EYEWEAR Normal Contact Lens Solution
P10403LHVFJ	EYEWEAR Sensitive Contact Lens Solution