

IZJAVA O SUKLADNOSTI *DECLARATION OF CONFORMITY*

1. PROIZVOĐAČ *MANUFACTURER*

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

2. PROIZVODI *PRODUCTS*

Rješenja za kontaktne leće i kapi za podmazivanje očiju prema priloženom popisu.
Contact lens care solutions and drops for eye lubrication as annex list.

3. POSTAUPAK PROCJENE SUKLADNOSTI *CONFORMITY ASSESSMENT ROUTE*
MDD 93/42/EEC i naknadne izmjene Prilog II.
MDD 93/42 EEC & s.a.s. Annex II

4. KLASIFIKACIJA *CLASSIFICATION*
Klasa IIb u skladu s MDD 93/42/EEC i kasnijim izmjenama Prilog IX Pravilo 15
Class IIb in compliance MDD 93/42 EEC & s.a.s. Annex IX Rule 15

5. IZJAVA *DECLARATION*
Ovim pod našom odgovornošću izjavljujemo da gore navedeni proizvodi udovoljavaju zahtjevima MDD 93/42/EEC i naknadnih izmjena. Sva prateća dokumentacija čuva se u prostorijama proizvođača i u skladu je s harmoniziranim standardima navedenim u nastavku.
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.

Također jamčimo *We also assure*

Primjena sustava osiguranja kvalitete u skladu sa zahtjevima MDD 93/42/EEC i s.m.i.
Priloga II.

The application of the Quality Assurance system complies with the requirements of MDD 93/42 EEC & s.a.s. Annex II
Usklađenost s bitnim zahtjevima prema MDD 93/42/EEC i naknadnim izmjenama i dopunama Priloga I.
The compliance with the essential requirements as MDD 93/42 EEC & s.a.s. Annex I

6. OBJAVLJENO TIJELO *NOTIFIED BODY*

ICIM Piazza Don E. Mapelli, 75 20099 Sesto San Giovanni 

0425

7. CE SVJEDODŽNICA *EC CERTIFICATE*

Br. 0425-MED-004157-00 od 28. listopada 2020. Rok isteka 31-12-2028.
N°0425-MED-004157-00 of 28 10-2020 expired 31-12-2028

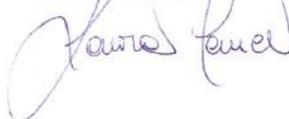
Ova izjava odnosi se na serije proizvoda proizvedene unutar razdoblja valjanosti i trajanja gore navedenog ICIM EC certifikata.

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

ROVIGO 30 10 2025

Zakoniti zastupnik
Legal representative

Amministratore Delegato
Laura CENCE





Vrsta / Type: Oftalmička otopina za pohranu i čišćenje kontaktnih leća / Ophthalmic solutions, for the care and conservation of contact lenses

Razred / Class: IIb

Višenamjenska rješenja / Multipurpose solutions 104 xx

Uzorski kod / Model code	Naziv modela / Model name
P10402LHVFJ	EYEWEAR Normal Contact Lens Solution
P10403LHVFJ	EYEWEAR Sensitive Contact Lens Solution