

IZJAVA O SKLADNOSTI DECLARATION OF CONFORMITY

1. PROIZVAJALEC *MANUFACTURER*

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

2. IZDELKI *PRODUCTS*

Raztopine za kontaktne leče in kapljice za mazalno mazilo za oči, kot je navedeno v priloženem seznamu.

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

3. POTEK OCENJEVANJA SKLADNOSTI *CONFORMITY ASSESSMENT ROUTE*

MDD 93/42/CEE & s.m.i. Priloga II.

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

4. KLASIFIKACIJA *CLASSIFICATION*

Razred IIb v skladu z MDD 93/42/EEG & s.m.i. Priloga IX Pravilo 15

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

5. IZJAVA *DECLARATION*

Na lastno odgovornost izjavljamo, da so zgoraj navedeni izdelki v skladu z zahtevami direktive MDD 93/42/EEG in njenih sprememb. Vsa dodatna dokumentacija je shranjena v pisarnah proizvajalca in je v skladu z veljavnimi usklajenimi standardi, navedenimi spodaj.

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 in force 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.

Poleg tega zagotavljamo: *We also assure*

Uporabo sistema zagotavljanja kakovosti v skladu z zahtevami MDD 93/42/EEG in spremembami Priloge II.

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

Skladnost z bistvenimi zahtevami iz MDD 93/42/EEG in spremembami Priloga I.

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

6. OBVESTILNI ORGAN *NOTIFIED BODY*

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



0425

7. CERTIFIKAT CE *EC CERTIFICATE*

Št. 0425-MED-004157-00 z dne 28. 10. 2020 Veljavnost do 31. 12. 2028

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

Ta izjava se nanaša na serije izdelkov, proizvedene v obdobju veljavnosti in trajanja zgoraj navedenega certifikata CE ICIM.

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 zastopnik

Legal representative

Amministratore Delegato

Laura CENCE



Tipologija / Type: Oftalmološke raztopine za shranjevanje in čiščenje kontaktnih leč / Ophthalmic solutions, for the care and conservation of contact lenses

Razred / Class: IIb

Večnamenske rešitve / Multipurpose solutions 104 xx

Model code / Model code	Ime modela / Model name
P10402LHVFJ	EYEWEAR Normal Contact Lens Solution
P10403LHVFJ	EYEWEAR Sensitive Contact Lens Solution