EC DECLARATION of CONFORMITY

Manufacturer name	**Fidia Farmaceutici S.p.A.**
Manufacturer address	Via Ponte della Fabbrica, 3/A 35031 Abano Terme (PD) – Italy
Name of device	**FLUOROFTA**
Description	Ophthalmic sterile solution for the tear film coloration
Intended use	**FLUOROFTA** is indicated for the tear film staining, which is suitable to facilitate the removal of a foreign body.
Presentation and format	SOLUTION 0,5% FLUORESCEIN 5 single-dose containers 30 single-dose containers (6 x 5 single-dose strips)

PRODUCT NAME	PRESENTATION	FORMAT	CODE
FLUOROFTA	SOLUTION 0,5% FLUORESCEIN	30 single-dose containers (6 x 5 single-dose strips)	TF24-01-1G
FLUOROFTA	SOLUTION 0,5% FLUORESCEIN	5 single-dose containers	TF24-01-1B

Classification (according to Dir. 93/42/EEC as amended)	Class IIa – Rule 6
Technical file reference	TF24 – FLUOROFTA and related trade names

I, the undersigned, hereby declare, under my sole responsibility, that the medical device specified above conforms with the relevant provisions of Directive 93/42/EEC subsequent amendments and integrations which apply to it.

This declaration is supported by:
– Annex V (Production QS) EC certificate no. QPZ-1953-21 valid until 26-05-2024, issued by ISS ON 0373.

Place: Abano Terme (PD)
Date: 18/05/2021
DoC Expiry date: 26/05/2024

Enrico Pozzi
Qualified Person

fidia

LIST OF APPLICABLE NORMATIVES AND STANDARDS

CATEGORY	REFERENCE	DESCRIPTION
System	Directive 93/42/EEC as amended	Medical Device Directive
	EN ISO 13485:2016	Quality Systems
	Farmacopea Ufficiale Italiana, curr. ed.	
	British Pharmacopeia, curr. ed.	
	European Pharmacopoeia, curr. ed.	
	United States Pharmacopoeia, curr. ed.	
	EN ISO 14971 :2012	Application of Risk Management to Medical Device
Biological Evaluation	EN ISO 10993-1:2009	Biological evaluation of medical devices – Evaluation and testing.
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-10:2013	Biological evaluation of medical devices. Part 10: Tests for irritation and delayed-type hypersensitivity.
Stability	ICH Q1A (R2)	Stability testing of New drug substances and products Q1A (R2)
	WHO Stability Guideline	Stability testing of active pharmaceutical ingredients and finished pharmaceutical products
Clinical Evaluation	MEDDEV 2.7/1 rev.4	Clinical evaluation: A guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
Labelling	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
	ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
Sterilization	UNI EN 556-2:2005	Sterilization of Medical devices – Requirements for medical devices bearing the indication "Sterile" - Part 2: Requirements form medical devices manufactured in asepsis
	ISO 13408-1:2003	Aseptic processing of health care products — Part 1: General requirements
	EN ISO 11737-1:2013	Sterilization of medical devices – Microbiological Methods – Part 1: Determination of a population of microorganisms on products.
	EN ISO 11737-2:2013	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

* The version in force when the tests have been performed were EN ISO 10993-1:1994, EN ISO 10993-5:1999; EN ISO 10993-10:2004. A gap analysis has been performed versus the current versions of the standards. The modifications brought change neither the scientific principle nor the substantial methodology in the new versions of the standards; therefore, it has been concluded that the tests already performed are still valid.