Version n°_01

EC DECLARATION OF CONFORMITY

Manufacturer's name: Manufacturer's address:	Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica, 3/A 35031 Abano Terme (PD) – Italy
Name of device:	**HYALO4 CARE** Cream
Description:	Topical preparation for wound treatment
Intended use:	**HYALO4 CARE** Cream is indicated for the management of cutaneous irritations and lesions. In particular, it is intended to cover acute wounds (donor sites and post-operative incisions, first and second degree burns) and chronic wounds (vascular and metabolic ulcers and pressure sores).
Presentation:	**HYALO4 CARE** Cream 0.2% cream is supplied in collapsible aluminium tubes containing 15g – 25g –30g and 100g of cream. Each tube is inserted in a cardboard box. Instructions for use are included in the package.

PRODUCT NAME	PRESENTATION	FORMAT	CODE
HYALO4 CARE	Cream	15g	AQA9-00-1A
HYALO4 CARE	Cream	25g	AQA9-00-1B
HYALO4 CARE	Cream	30g	AQA9-00-1C
HYALO4 CARE	Cream	100g	AQA9-00-1D

Classification: (according to Dir. 93/42/EEC subsequent amendments and integrations)	Class IIb – Rule 4
Technical file reference:	CE file named TF AQA9-1

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.

Fidia farmaceutici S.p.A. Via Ponte della Fabbrica 3/A, 35031 Abano Terme (PD) – Italia. Iscr. Reg. Imp. PD – CF/P.IVA 00204260285 - Codice Destinatario: **KØROACV** – Cap.Soc. € 36.120.000 int. vers. – CCIAA PD n.80793 - T +390498232111 – F +39049810653 – info@fidiapharma.it – www.fidiapharma.com – PEC DL@pec.fidiapharmapec.it
Società soggetta all'attività di direzione e coordinamento di P&R S.p.A. Strada Rivoltana Km 6/7 – 20090 Rodano (MI) Iscr. Reg. Imp. MI – CF/P.IVA 00651030181 – Cap. Soc. € 12.000.000 int. vers. – CCIAA MI n. 1572270

This declaration is supported by the Full Quality Assurance System (Annex II excluding point 4) EC certificate no. G1 044273 0009 rev. 00, valid until 26/05/2024, issued by TUV Sud Product Service, RidlerstraBe 65, 80339 Munchen, NB n. 0123.

Place: Abano Terme (PD)
Date: 30th June 2023
DoC Expiry date: May 26th, 2024

Enrico Pozzi
Qualified Person

LIST OF APPLICABLE NORMATIVES AND STANDARDS

No	Category	Reference	Title
1	System	Directive 93/42/EEC (as amended)	Medical Devices Directive
		ISO 9001:2015	Quality Systems Management
		EN ISO 13485:2016 + A11:2021	Quality Systems Management for Medical Devices
		EN ISO 14971:2019+A11: 2021	Application of Risk Management to Medical Devices
		IEC 62366-1: 2015+ AMD1:2020	Application of usability engineering to medical devices
2	Manufacturing	EudraLex - Volume 4 – Part I	Good Manufacturing Practice (GMP) guidelines - Basic Requirements for Medicinal Products
		EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1,Corr.1 (2016)	Guideline on process validation for finished products - information and data to be provided in regulatory submissions
		21 CFR 820, current ed.	Medical Devices, Current Good Manufacturing Practice – Quality System Regulation
		European Pharmacopoeia current edition	<2.6.12> Microbial examination of non-sterile products: microbial enumeration tests <2.6.13> Microbial examination of non-sterile products: test for specified micro-organisms <3.1> Materials used for the manufacture of containers <3.2> Containers <5.1.4> Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
		ISO 2859-1:1999	Sampling procedures for inspection by attributes – Part 1: sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

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No	Category	Reference	Title
		Regulation EC n. 1272/2008 (CLP), Annex I	Regulation on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Annex I: Classification and labelling requirements for hazardous substances and mixtures.
3	Stability	CPMP/QWP/122/02 rev.1 (2003)	Guideline on Stability Testing: Stability Testing of Existing Substances and Related Finished Products
		CPMP/QWP/2934/99 (2001)	Note for guidance on in-use stability testing of human medicinal products
		ICH Q1A(R2) (2003)	Stability testing of new drug Substances and Products
4	Biological evaluation	EN ISO 10993-1:2020	Biological Evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process.
		EN ISO 10993-2: 2006	Biological evaluation of medical devices – Part 2: Animal welfare requirements.
		EN ISO 10993-5:2009	Biological Evaluation of medical devices – Part 5: Tests for *in Vitro* Cytotoxicity.
		EN ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation.
		ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization.
		EN ISO 10993-11:2018	Biological Evaluation of medical devices - Part 11: Tests for systemic toxicity.
		EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.
		EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances.

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No	Category	Reference	Title
		EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.
		EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation.
		ICH Q3C(R8) (2021)	Guidelines for Residual Solvents.
		OECD Guideline n439 (2015)	*In vitro* Skin irritation: Reconstructed human Epidermis Test Method
5	Packaging	Decreto Ministeriale of 21 March 1973 and subsequent amendments	Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale .
6	Labelling	EN ISO 20417: 2021	Information supplied by the manufacturer of medical devices
		EN ISO 15223-1:2021	Graphical Symbols for Use in the Labelling of Medical Devices
		Reg. (CE) n. 1223/2009, Annex VII	REGULATION (EC) N° 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.
7	Clinical investigation	EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
		MEDDEV 2.7/1 rev 4 (2016)	Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
		MEDDEV 2.7/3 rev.3 (2015)	Clinical investigations: serious adverse event reporting - SAE reporting form
		MEDDEV 2.12/2 rev 2 (2012)	Post Market Clinical Follow-up

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