

## EC DECLARATION OF CONFORMITY

Manufacturer's name: Fidia Farmaceutici S.p.A.  
Manufacturer's address: Via Ponte della Fabbrica, 3/A  
35031 Abano Terme (PD) – Italy

Name of device: **HYALO4 CARE Gel**

Description: Topical preparation for wound treatment

Intended use: HYALO4 CARE Gel is indicated for the management of cutaneous irritations and lesions. In particular, it is intended to cover acute and chronic wounds (abrasions, donor sites and post-operative incisions, first and second degree burns, vascular and metabolic ulcers and pressure sores) and to provide a moist wound environment, thus protecting against abrasions, friction and desiccation.

Presentation: HYALO4 CARE 0.2% gel is supplied in collapsible aluminium tubes containing 30g and 100g of gel. Each tube is inserted in a cardboard box. Instructions for use are included in the package.

PRODUCT NAME	PRESENTATION	FORMAT	MODEL NUMBER
HYALO4 CARE	Gel	30g	AQA9-09-2A
HYALO4 CARE	Gel	100g	AQA9-09-2B

Classification: Class IIb – Rule 4  
(according to Dir. 93/42/EEC subsequent amendments and integrations)

Technical file reference: CE file named TF AQA9-2

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.

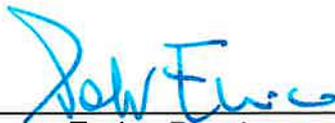


This declaration is supported by the Full Quality Assurance System (Annex II excluding point 4) EC certificate no. G1 044273 0009 rev. 00, valid until 26/05/2024, issued by TUV Süd Product Service, Ridlerstraße 65, 80339 München, NB n. 0123.

Place: Abano Terme (PD)

Date: June 30<sup>th</sup>, 2023

DoC Expiry date: May 26<sup>th</sup>, 2024

  
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Enrico Pozzi  
Qualified Person