

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 CREAM PLUS**
HYALO4 CARE GAUZE-PADS PLUS

Description: Topical preparation for wound treatment

Intended use: HYALO4 CARE PLUS is indicated for the management of skin lesions, especially those at high risk of infection. In particular, it is intended to cover acute and chronic wounds (first and second degree burns, vascular and metabolic ulcers and pressure sores) and to provide a moist microbe-free wound environment.
HYALO4 CARE PLUS can be used on non-infected wounds to help in preventing infection and, following successful treatment of infected wounds, to help prevent the reoccurrence of infection.

Presentations and codes: See addendum

Classification
(according to Dir. 93/42/EEC subsequent amendments and integrations): Class III – Rule 13 and rule 4

Technical file reference: CE file named TF AQ14.

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:

- Type examination (Annex III) EC certificate no. 2114366TE01, valid until 26/05/2024, issued by DEKRA, NB no. 0344;
- Approval of production quality assurance system (Annex V) EC certificate no. 35326 rev. 3, valid 26/05/2024, issued by LNE/G-MED, NB no. 0459.

Place : Abano Terme (PD)
DoC date of issue: 21st August 2023

DoC Expiry date: 26th May 2024


Rossella Pellizzari
Qualified Person

Addendum

Product Name	Presentation	Format	Code
HYALO4 CARE CREAM PLUS	CREAM	25g	AQ1411_1A
HYALO4 CARE CREAM PLUS	CREAM	100g	AQ1411_1B
HYALO4 CARE GAUZE-PADS PLUS	GAUZE PADS	10x10 cm	AQ1411_2A
HYALO4 CARE GAUZE-PADS PLUS	GAUZE PADS	10x20 cm	AQ1411_2B
HYALO4 CARE GAUZE-PADS PLUS	GAUZE PADS	20x 30 cm	AQ1411_2C