Rev_01

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 START**
Description:	**HYALO4 CARE START** is a semi-solid preparation for topical application in the form of an ointment based on sodium hyaluronate (hyaluronic acid sodium salt) as main component and collagenase enzyme.
Intended use:	**HYALO4 CARE START** is indicated for the local management of chronic ulcers (i.e. pressure sores, vascular ulcers of the leg, diabetic ulcers). In particular, it is intended to provide an optimal moist environment and wound bed preparation that support the natural healing process.

Code and Presentation:

PRESENTATION	FORMAT	CODE
Ointment 0.2%	30 g tube	HQC6-05-1A

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 HQC6
Standards applied:	In TF HQC6 §D2

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 and subsequent amendments and integrations which apply to it. Furthermore, the medical device also complies with the provisions of Article 120 of Regulation (UE) 2017/745.
This declaration is supported by:

- Full Quality Assurance System (Annex II) EC certificate no. EPG-0356-21_AnxII (4) and QCT-0168-21 Add.01-21_AnxII (except 4), valid until 26/05/2024, issued by Notified Body 0373 Istituto Superiore di Sanità.
- The certificate validity is extended up to December 31st, 2027, as per Regulation (EU) 2023/607 amending Regulations (EU) 2017/745.

Place: Abano Terme (PD)
Date: 25/07/2024
Expiry Date: 31/12/2027

Rossella Pellizzari
Head of Plant & Qualified Person