EC Design Examination Certificate
Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

GRAFTYS

Eiffel Park Bat. D 415 rue Claude Nicolas Ledoux Pole d'Activités d'Aix en Provence 13854 AIX EN PROVENCE Cedex 3 France

For Product Family

Injectable Resorbable Calcium Phosphate Bone Void Fillers: GRAFTYS®HBS, GRAFTYS® QUICKSET

GMDN Code: 17751

CONCLUSION of EXAMINATION:

NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)

Registration Number:	**252.798**
Original Approval:	**09 December 2009**
Last Amended on:	**08 April 2020**
Remains valid until:	**26 May 2024**

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner. Approved model numbers are included in the associated attachment

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the product must receive further approval from NSAI.

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.