



NSAI

Certificate of Registration of Quality Management System to ISO 13485:2016

Australia - Therapeutic Goods (Medical Devices) Regulations, 2002,
 Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure.
Brazil - RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
Canada - Medical Devices Regulations - Part 1- SOR 98/282
United States - 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D,
 21 CFR 820 - Quality System Regulation

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

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

D-U-N-S: F004679

has been assessed and deemed to comply with the requirements of the above standard and regulations in respect of the scope of operations given below:

The Design, Manufacture and Distribution of Sterile Calcium Phosphate Resorbable Bone Void Fillers and related Delivery Systems.

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4529)

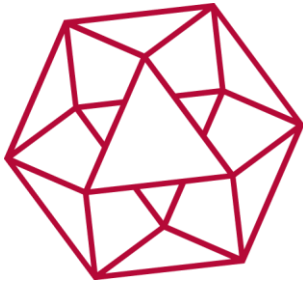
Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Certificate Number: MP19.4529 / Rev 1
Certification Granted: 2020/05/12
Effective Date: 2020/05/12
Expiry Date: 2023/05/11



National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800
National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412
All valid certifications are listed on NSAI's website - www.nsaiinc.com
The continued validity of this certificate may be verified under "Approved Client Listing"



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Annex to Certificate Number: MP19.4529 / Rev 1

Scope of Registration:

The Design, Manufacture and Distribution of Sterile Calcium Phosphate Resorbable Bone Void Fillers and related Delivery Systems.

Activity

Location

Headquarters, Design, Manufacturing,
Distribution

GRAFTYS
Eiffel Park Bât D
415 rue Claude Nicolas Ledoux
Pole d'Activités d'Aix en Provence 13854
AIX EN PROVENCE Cedex 3
France
File No.: MP19.4529
D-U-N-S: F004679

Manufacturing, Distribution

GRAFTYS
Eiffel Park Bât C
415 rue Claude Nicolas Ledoux
Pole d'Activités d'Aix en Provence
13854 AIX EN PROVENCE Cedex 3
France
File No.: MP19.4529/A
D-U-N-S: F004679

Administration

GRAFTYS
48 Rue Auguste Piccard
Gosselies
Belgium
File No.: MP19.4529/C
D-U-N-S: F004680

Verified by:
Operations Manager