



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

Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (,as applicable)

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:

Hu-Friedy Manufacturing Co., LLC

3232 N Rockwell Street

Chicago, IL 60618

USA

Facility ID: F005181

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:

Design, Manufacture, and Distribution of Devices used in Dental Applications Including: Cartridge Syringe, Surgical Burs and Drills, Sterile Absorbable PGA Sutures, Sterile Fast Absorbing PGA Sutures, Sterile Absorbable Gut Sutures, Sterile Non-Absorbable Nylon Sutures, Sterile Non-Absorbable Silk Sutures, Sterile Non-Absorbable Polypropylene Sutures, Sterile Non-Absorbable Polyester Sutures, Stainless Steel Crowns; Ultrasonic Generators, Handpieces and Ultrasonic Scaler Inserts/Tips, and Sterile Blades; Service of Ultrasonic Generators, Handpieces, and Inserts/Tips

Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.8418)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Certificate Number: MP19.8418 / Rev 1
Certification Granted: 2020/10/02
Effective Date: 2021/11/10
Expiry Date: 2022/10/10



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.nsa-inc.com The continued validity of this certificate may be verified under "Approved Client Listing"



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Annex to Certificate Number: MP19.8418 / Rev 1

Scope of Registration:

Design, Manufacture, and Distribution of Devices used in Dental Applications Including: Cartridge Syringe, Surgical Burrs and Drills, Sterile Absorbable PGA Sutures, Sterile Fast Absorbing PGA Sutures, Sterile Absorbable Gut Sutures, Sterile Non-Absorbable Nylon Sutures, Sterile Non-Absorbable Silk Sutures, Sterile Non-Absorbable Polypropylene Sutures, Sterile Non-Absorbable Polyester Sutures, Stainless Steel Crowns; Ultrasonic Generators, Handpieces and Ultrasonic Scaler Inserts/Tips, and Sterile Blades; Service of Ultrasonic Generators, Handpieces, and Inserts/Tips

Activity

Location

Headquarters, Design,
Manufacture, Distribution,
Purchasing & Servicing

Hu-Friedy Manufacturing Co., LLC
3232 N Rockwell Street
Chicago, IL 60618
USA
File No.: MP19.8418
Facility ID: F005181

Distribution, Purchasing &
Packaging

Hu-Friedy Manufacturing Co., LLC
1666 E Touhy Avenue
Des Plaines, IL 60018
USA
File No.: MP19.8418/A
Facility ID: F005181

**Verified by:
Operations Manager**