



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Hu-Friedy Manufacturing Co., LLC
3232 N Rockwell Street
Chicago, IL 60618
USA

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

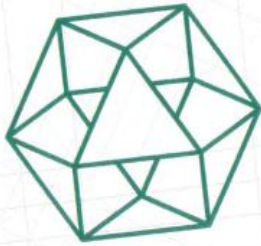
Design, Manufacture, and Distribution of Devices used in Dental Applications Including: Cartridge Syringe, Surgical Burrs and Drills, Sterile Absorbable PGA Sutures, Sterile Fast Absorbing PGA Sutures, Sterile Absorbable Gut Sutures, Sterile Non-Absorbable Nylon Sutures, Sterile Non-Absorbable Silk Sutures, 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
Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.8418)

Approved by:
Geraldine Larkin
Chief Executive Officer

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

Registration Number: MD19.8418
Certification Granted: October 02, 2020
Effective Date: October 11, 2021
Expiry Date: October 10, 2022





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Annex to Certificate Number: MD19.8418

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.: MD19.8418

Distribution, Purchasing &
Packaging

Hu-Friedy Manufacturing Co., LLC
1666 E Touhy Avenue
Des Plaines, IL 60018
USA
File No.: MD19.8418/A

**Verified by:
Operations Manager**