



# 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:

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**Design, manufacture and distribution of devices used in dental applications including: non-sterile dental hand instruments, Ultrasonic scaler insert/tips and aspirator tips and instrument trays.**

**Distribution of devices used in dental applications including: Cartridge Syringes, 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 and Handpieces, Sterilization Monitoring and Assurance Products, Including Chemical Indicators, Chemical Integrators, Biological Indicators, Sterilization Packaging and Instrument Cleaning and storage.**

**Service of dental instruments including, Hand Instruments, 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:  
Kevin Mullaney  
Director of Certification

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Registration Number: MD19.8418  
Certification Granted: April 13, 2021  
Effective Date: April 13, 2024  
Expiry Date: April 12, 2027





# NSAI

**Annex to Certificate Number: MD19.8418**

**Scope of Registration:**

**Design, manufacture and distribution of devices used in dental applications including: non-sterile dental hand instruments, Ultrasonic scaler insert/tips and aspirator tips and instrument trays.**

**Distribution of devices used in dental applications including: Cartridge Syringes, Sterile Absorbable PGA Sutures, Sterile Fast Absorbing PGA Sutures, Sterile Absorbable Gut Sutures, Sterile Non-Absorbable Nylon Sutures, Sterile Non-Absorbable Silk Sutures, Sterile NonAbsorbable Polypropylene Sutures, Sterile Non-Absorbable Polyester Sutures, Stainless Steel Crowns, Ultrasonic Generators and Handpieces, Sterilization Monitoring and Assurance Products, Including Chemical Indicators, Chemical Integrators, Biological Indicators, Sterilization Packaging and Instrument Cleaning and storage.**

**Service of dental instruments including, Hand Instruments, 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

Administration, Servicing, Packaging & Distribution

Hu-Friedy Manufacturing Co., LLC  
Bogenstrasse 6 – 8  
78576 Emmigen – Liptingen  
Germany  
File No.: MD19.8418/B

**Verified by:  
Director of Certification**