



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: non-sterile dental hand instruments, Ultrasonic scaler insert/tips and aspirator tips.

Distribution of devices used in dental applications including: Cartridge Syringes, 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 NonAbsorbable Polypropylene Sutures, Sterile Non-Absorbable Polyester Sutures, Stainless Steel Crowns, Ultrasonic Generators and Handpieces.

Service of dental instruments including 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: April 13, 2021
Effective Date: December 28, 2021
Expiry Date: April 12, 2023





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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.

Distribution of devices used in dental applications including: Cartridge Syringes, Surgical Burrs and Drills, Sterile Absorbable PGA Sutures, Sterile Fast Absorbable 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.

Service of dental instruments including 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
Kleines Öschle 8
78532 Tuttlingen
Germany
File No.: MD19.8418/B

**Verified by:
Operations Manager**