



# 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: 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. 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 2

Certification Granted: 2020/10/02

Effective Date: 2021/12/28

Expiry Date: 2023/10/10



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.nsaiinc.com](http://www.nsaiinc.com) The continued validity of this certificate may be verified under "Approved Client Listing"



# NSAI

## **Annex to Certificate Number: MP19.8418 / Rev 2**

### **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 Non-Absorbable 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.: 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**