



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. 665/2022 RDC ANVISA n. 551/2021 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 and instrument trays.

Distribution of devices used in dental applications including: Cartridge Syringes, 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, 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. MP19.8418)

Approved by:

Kevin Mullaney

Director of Certification

Certificate Number: MP19.8418 / Rev 1

Certification Granted: 2020/10/02

Effective Date: 2024/04/13

Expiry Date: 2027/04/12



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 The continued validity of this certificate may be verified under "Approved Client Listing"



NSAI

Annex to Certificate Number: MP19.8418 / Rev 1

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.: 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:
Director of Certification**