

Certificate Number US18/711041492

The management system of

## Hu-Friedy Mfg. Co., LLC

3232 N. Rockwell Street,  
Chicago, IL, 60618, United States

Dun & Bradstreet D-U-N-S identification number: 00-508-5972

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



## MDSAP (ISO 13485:2016)

Australia  
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

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

United States  
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

**See second and subsequent pages for the scope.**

This certificate is valid from  
Effective Date: 2018-11-15 until Expiry Date: 2021-10-10  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2021-07-05  
Issue 2. Certified since 2018-10-11

This is a multi-site certification.  
Additional site details are listed on subsequent pages.

Authorised by H Crick  
Business Manager

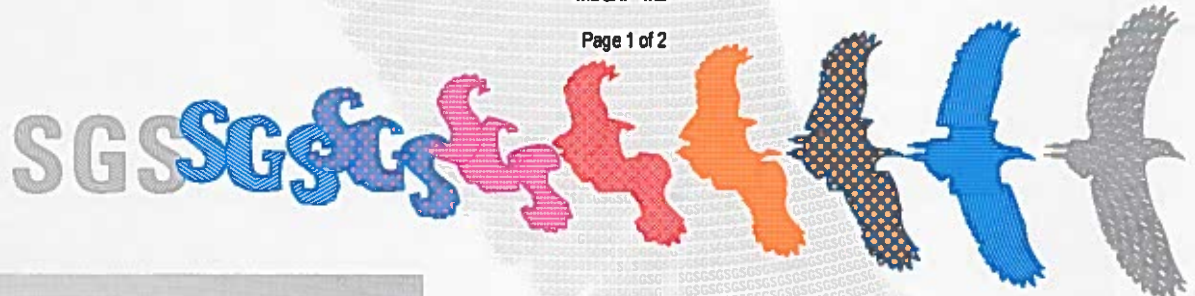


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MDSAP M2

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# Hu-Friedy Mfg. Co., LLC

## MDSAP (ISO 13485:2016)

Issue 2

Detailed scope

**Design, manufacture, and distribution of devices used in dental applications including: cartridge syringe, surgical burs 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, hand pieces and Inserts/tips.**

**The applicable scope for Brazil and Japan:**

**Design, manufacture and distribution of devices used in dental applications including: non-sterile dental hand Instruments and related accessories.**

**The applicable scope for USA and Australia:**

**Design, manufacture and distribution of devices used in dental applications including: non-sterile dental hand Instruments and related accessories.**

**Distribution of surgical burs 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, and sterile blades.**

**Service of ultrasonic generators, hand pieces and Inserts/tips.**

Additional facilities

**1666 E. Touhy Avenue, Des Plaines, IL, 60018, United States  
Dun & Bradstreet D-U-N-S identification number: 04-551-5092**

**Distribution of devices used in dental applications including: cartridge syringe, surgical burs 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.**

