

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 (OR 21 CFR 820.180 and 198) / 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: 11 October 2018 until Expiry Date: 10 October 2021
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 5 July 2021
Issue 1. Certified since 11 October 2018

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 1

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, handpieces 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.

Additional facilities

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

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, handpieces and inserts/tips.

