



Certificate US97/10656

The management system of

# Hu-Friedy Mfg. Co., LLC

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



has been assessed and certified as meeting the requirements of

## ISO 13485:2003 EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 10 September 2015 until 5 July 2018  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 5 July 2018  
Issue 22. Certified since 5 July 1997

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

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# Hu-Friedy Mfg. Co., LLC

## ISO 13485:2003 EN ISO 13485:2012



Issue 22

Detailed scope

**Design, manufacture and distribution of devices used in dental applications including: non-sterile dental hand instruments and related accessories, ultrasonic generators, handpieces and ultrasonic scalers inserts/tips. Manufacture and Distribution of devices used in dental applications including: sterile scalpel blades, sterile absorbable sutures, sterile non-absorbable sutures, surgical aspirator tips, and stainless steel crowns. Servicing of dental hand instruments and dental equipment.**

Additional facilities

**Zweigniederlassung Deutschland, Kleines Öschle 8, D-78532 , Tuttlingen, Germany**

**1666 E. Touhy Avenue, Des Plaines, IL, 60018-3607, United States**

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