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 13485:2016
EN ISO 13485:2016

For the following activities

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

This certificate is valid from 20 August 2018 until 05 July 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 05 July 2021
Issue 23. Certified since 05 July 1997

Expiry date of last certificate: 05 July 2018
End date of last recertification audit: 26 April 2018

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

Authorised by

SGS United Kingdom Ltd
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HC SGS 13485 2016 0118 M2

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Hu-Friedy Mfg. Co., LLC

ISO 13485:2016
EN ISO 13485:2016

Issue 23

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 burs and drills, surgical aspirator tips, stainless steel crowns. Servicing of dental hand instruments and dental equipment.

Additional facilities

Zweigniederlassung Deutschland, Kleines Oschle 8, D-78532, Tuttlingen, Germany

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

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