EC Certificate Full Quality Assurance System: US97/10657

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

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

This certificate is valid from 30 August 2018 until 05 July 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 05 July 2018
Issue 23. Certified since 05 July 1997

Certification is based on reports numbered WWMC/07885

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 02 0315 M2

Hu-Friedy Mfg. Co., LLC

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 23

Detailed scope

Devices used in dental applications including: Magnetostrictive ultrasonic inserts, Stainless Steel Crowns, Piezoelectric tips, Dental Aspirators.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

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

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