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

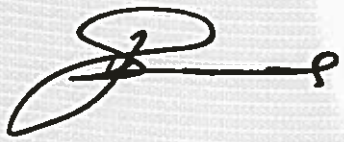
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 10 September 2015 until 5 July 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 5 July 2018
Issue 21. Certified since 5 July 1997

Certification is based on reports numbered WW/MC 07886

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 21

Detailed scope

Devices used in dental applications including:

Surgical aspirator tips. Surgical burrs and drills. Ultrasonic generators, handpieces, scaler inserts and tips. Sterile scalpel blades.

Sterile non-absorbable sutures (silk, nylon, polyester, polypropylene). Sterile absorbable sutures (polyglycolic acid), sterile fast absorbing sutures (polyglcolic acid).

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