



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 WW/MC/07886

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

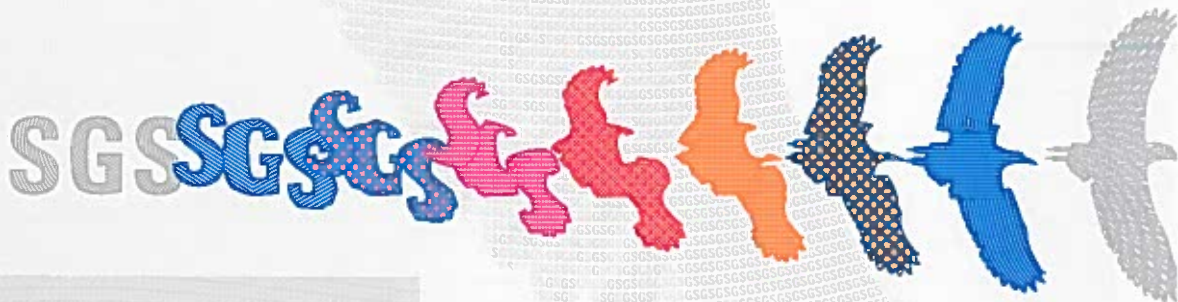
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Service accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

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



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.