

EC Certificate Production Quality Assurance System: Certificate
US13/82716

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 V

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 3. 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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EC Certificate Production Quality Assurance System: Certificate
US13/82716, continued

Hu-Friedy Mfg. Co., LLC

Directive 93/42/EEC on medical devices, Annex V

Issue 3

Detailed scope

Stainless steel crowns.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III 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**

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