

EC Design Examination Certificate: Certificate US98/13689

Hu-Friedy Mfg. Co., LLC

3232 N. Rockwell Street,
Chicago, IL, 60618, United States

Device Identification:

PERMA SHARP® Polyglycolic Acid (PGA) Absorbable Surgical Sutures

Intended Purpose of Device:

Sterile sutures for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures. Not for use in cardiovascular or neurological procedures.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 31 January 2014 until 6 July 2018
Issue 11

Certification is based on report number(s) WW/MC 202010 dated 6 January 2014

Addenda to that report have been issued on the following dates:

Addendum Date

Reason for Addendum

Authorised by

SGS United Kingdom Limited, Notified Body 0120

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