

EC Design Examination Certificate: Certificate US06/67956

## Hu-Friedy Mfg. Co., LLC

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

Device Identification:

Sterile PERMA SHARP ® Polyglycolic Acid Fast Absorbing (PGA FA) Sutures.

Intended Purpose of Device:

For use in superficial soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. These sutures are not for use in ligation, ophthalmic, 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 1 October 2011 until 1 April 2016 Issue 3

Certification is based on report number(s) WW/PCI 213373 dated 5 August 2011 Addenda to that report have been issued on the following dates:

Reason for Addendum

Addendum Date

SGSSGS

Authorised by

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