

The management system of

# Kirwan Surgical Products LLC

180 Enterprise Drive, Marshfield, MA, 02050, 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

- Non-sterile Reusable Bipolar General use Forceps,**
- Non-Sterile Reusable Pencils/Probes.**
- Sterile Disposable Microsurgical Forceps,**
- Non-sterile Reusable Microsurgical Forceps**
- Sterile Disposable Ophthalmic Pencils,**
- Sterile Disposable Monopolar Suction Coagulator,**
- Non-sterile 70 Watt Bipolar Coagulator**
- Sterile Disposable Bipolar Forceps with Cords,**
- Sterile Disposable Bipolar Suction Coagulator,**
- Sterile Disposable Microdissection Needle.**
- Sterile Disposable Battery Cautery.**

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.

This certificate is valid from 24 July 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.  
Issue 4. Certified since 09 June 2013 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WWMW 606189

Authorised by

### SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

