



Ms. Karen Risley  
Facet Technologies, LLC  
101 Liberty Industrial Parkway  
McDonough, GA, 30253

WW/ME 08073  
8 June 2015

Dear Ms. Risley:

Following the recent re-appraisal of your Company's Management System, I am pleased to inform you that the System in operation conforms to the requirements of ISO 13485:2003, CMDCAS, MDD 93/42/EEC Annex II (excl sec 4) and Annex V SAO.

Enclosed is a copy of your Certificate. Duplicate copies of these can be purchased by contacting me.

Yours sincerely,

A handwritten signature in black ink that reads 'Laura Prioli'.

Laura Prioli  
Health Care/Medical Device Specialist  
laura.prioli@sgs.com

EC Certificate Full Quality Assurance System: US98/11987

The management system of

# Facet Technologies, LLC

101 Liberty Industrial Parkway,  
McDonough, GA, 30253, 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 10 June 2015 until 10 June 2020  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 May 2018

Issue 15. Certified since 4 February 1998

Certification is based on reports numbered WW/ME 08073

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd Systems & Services Certification  
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

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# Facet Technologies, LLC

## Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 15

Detailed scope

- Sterile single-use capillary blood lancets.**
- Sterile single-use safety capillary blood lancets.**
- Blood sampling system consisting of a non-sterile delivery unit with replaceable non-sterile cartridge containing sterile lancets.**
- Blood lancing system consisting of a non-sterile lancing device and sterile lancets.**

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

3900 North Commerce Drive, Atlanta, GA, 30322, United States

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The management system of

# Facet Technologies, LLC

101 Liberty Industrial Parkway,  
McDonough, GA, 30253, United States

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and  
maintaining sterile conditions.

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 10 June 2015 until 10 June 2020  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 May 2018

Issue 2. Certified since 4 February 1998

Certification is based on reports numbered WW/ME 08073

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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# Facet Technologies, LLC

## Directive 93/42/EEC

on medical devices, Annex V  
Restricted to the aspects of manufacture concerned with securing and  
maintaining sterile conditions.

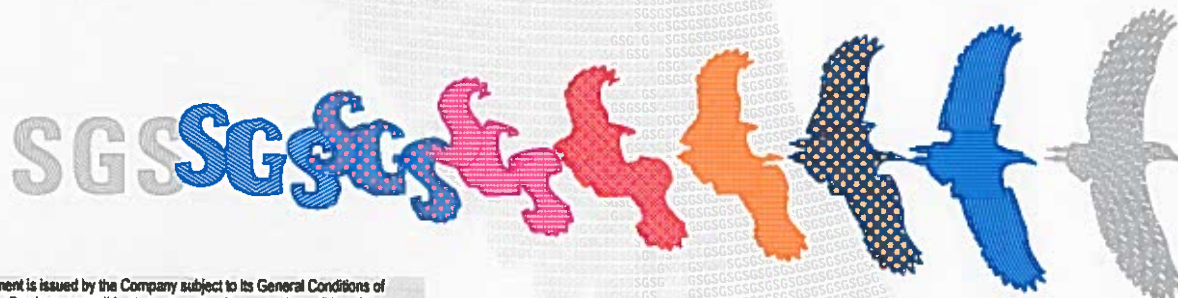
Issue 2

Detailed scope

**Class I Sterile : "Sterility aspects only - Restricted to the aspects of  
manufacture concerned with securing and maintaining sterile  
conditions"  
Sterile single-use pressure bandages.**

Additional facilities

**3900 North Commerce Drive, Atlanta, GA, 30322, United States**



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The management system of

## Facet Technologies, LLC

101 Liberty Industrial Parkway,  
McDonough, GA, 30253, United States

has been assessed and certified as meeting the requirements of

## ISO 13485:2003

For the following activities

**Design and manufacture of sterile single-use capillary blood lancets, integrated blood sampling system consisting of a non-sterile delivery unit with replaceable non-sterile cartridge containing sterile lancets and sterile single-use pen (hypodermic) needles.**

Effective Date 10 June 2015 Expiry Date 10 June 2018  
Re certification audit due before 13 May 2018  
Valid subject to satisfactory surveillance audits.  
Issue 6. Certified since 10 June 2009

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

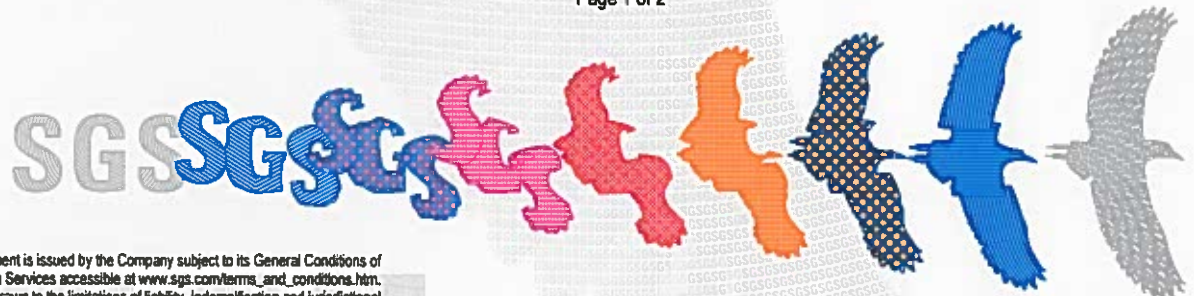
Authorised by  
Jan Saunders – Business Manager



SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)  
CMDCAS recognised registrar

SGS 13485 CMDCAS 0911 MS M2

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# Facet Technologies, LLC

## ISO 13485:2003

Issue 6



Additional facilities

3900 North Commerce Drive, Atlanta, GA, 30322, United States

**Scope: Design and administration of sterile single-use capillary blood lancets, integrated blood sampling system consisting of a non-sterile delivery unit with replaceable non-sterile cartridge containing sterile lancets and sterile single-use pen (hypodermic) needles.**



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The management system of

# Facet Technologies, LLC

101 Liberty Industrial Parkway,  
McDonough, GA, 30253, United States

has been assessed and certified as meeting the requirements of

## ISO 13485:2003 EN ISO 13485:2012

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 10 June 2015 until 10 June 2018  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 13 May 2018  
Issue 14. Certified since 4 February 1998

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

Authorised by

SGS United Kingdom Ltd Systems & Services Certification  
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SGS 13485-2 0614 M2

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# Facet Technologies, LLC

## ISO 13485:2003 EN ISO 13485:2012



Issue 14

Detailed scope

**Contract design of medical devices. Design and manufacture of sterile single use pressure bandages, blood lancing systems consisting of a non-sterile delivery units with replaceable non-sterile cartridges containing sterile lancets and integrated blood sampling system consisting of a non-sterile delivery system with replaceable non-sterile cartridge containing sterile lancets and sterile single-use pen (hypodermic) needles. Packaging of capillary blood lancets. Supply of own and private label devices and supplies for diabetic blood glucose monitoring.**

Additional facilities

**3900 North Commerce Drive, Atlanta, GA, 30322, United States**

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