EC Certificate Full Quality Assurance System: US98/11987

The management system of

Facet Technologies, LLC

3900 North Commerce Drive,
Atlanta, GA, 30344, 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 22 October 2015 until 10 June 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 13 May 2018
Issue 17. 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
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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 17

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

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

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