EC Certificate Full Quality Assurance System: US09/5582

The management system of

Halifax Biomedical Inc.

11493 Route 19,
Mabou, Nova Scotia, BOE 1X0, Canada

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 2 October 2015 until 27 April 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 October 2017
Issue 3. Certified since 27 April 2009

Certification is based on reports numbered WW/MC 601416

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

Halifax Biomedical Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 3

Detailed scope

Sterile Tantalum beads (passive radiopaque markers) for orthopaedic radiographic marking.

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

11513 Route 19, Mabou, Nova Scotia, BOE 1X0, Canada