EC Certificate Full Quality Assurance System: Certificate US15/842414

The management system of

Spiraltech-Superior Dental Implants, Inc.

875 N. Michigan Avenue, Suite 3106,
Chicago, IL, 60611, 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

Hex Connection sterile dental implant system, Conical Connection Sterile dental implant, One Piece sterile dental implant, orthodontics sterile implants; non sterile abutments, non sterile dental surgical caps and components, non sterile dental screws and non sterile dental surgical tools.

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 22 August 2017 until 13 November 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 21 January 2018
Issue 2. Certified since 13 November 2015

Certification is based on reports numbered WW/MC 606492

Authorised by

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