EC Certificate Full Quality Assurance System: Certificate US02/56962

The management system of

Ortho Technology, Inc.

4614 Pet Lane,
Suite D-101, Lutz, FL, 33559, 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

Orthodontic brackets, bands, components, elastomeric products, dental instruments, orthodontic wires, springs and attachments, dental burs and diamond discs, lingual retainers, bonding agents / adhesives and gel etchants.

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 29 July 2016 until 15 December 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 December 2018
Issue 9. Certified since 10 October 2002

Certification is based on reports numbered WW/ME 208138

Authorised by

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