



# ACE Surgical Supply Co., Inc.

1034 Pearl Street, Brockton, MA, 02301, 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

- ACE infinity Tri-Cam Dental Implant System, (including sterile implants and terminal or intermediary abutments)
- ACE infinity External Hexagon Dental Implant System (including sterile implants and terminal or intermediary abutments)
- ACE infinity Internal Hexagon Dental Implant System (including sterile implants and terminal or intermediary abutments)
- Tru-Fix Bone Screw System including sterile screws and foil and non-sterile mesh barrier membrane - used to stabilize and support bone graft or bone segments / provide fixed anchorage point for attachment orthodontic appliances
- ACE Minimark Dental Implant System (including sterile implants and terminal or intermediary abutments)

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 17 March 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2. Certified since 02 December 2005 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MC 212429

Authorised by

### SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

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