

The management system of

Tita-Link BVBA

Avenue de Hinnisdaellaan 2
1150 Sint-Pieters-Woluwe, Belgium

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

Sterile Bollard Skeletal Anchor to be placed in the mouth for use as an anchor in orthodontic procedures
(BUL21 / BUR21 / BLL16 / BLR16 / BHUL21 / BHUR21 / BHLL 16 / BHLR16/ BHUL18PED / BHUR18PED I BHUL19Y / BHUR19Y)

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 19 June 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 19 June 2020.

Certification is based on reports numbered BE/AMD 19/1131.QMD

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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