EC Certificate Full Quality Assurance System: Certificate US21/819944296

The management system of

Ortho Technology, Inc.

1 Southern CT, West Columbia, SC, 29169, 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

Metal Brackets and Buccal Tubes, Ceramic Brackets, Composite Brackets, Orthodontic Bands and Assemblies, Orthodontic Adhesives and Cement Systems, Orthodontic Wire Accessories including springs., ligature ties, crimpable ball hooks, and mini stops, Elastomerics, Auxiliaries, Intraoral Appliances

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 25 March 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 25 March 2021

Certification is based on reports numbered WW/MC 616874

Authorised by

Global Medical Devices Head of Notified Body

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