



EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-146

Issued to: Ortho Solutions LC dba DynaFlex
10403 International Plaza Drive, 63074 St. Ann, Missouri, USA
Product category: Orthodontic Brackets, Bands & Tubes
UMDNS: 16360, 16198, 16199
Product category: Orthodontic Archwires, Wires, Springs
UMDNS: 16204
Product category: Orthodontic Elastomeric Products
UMDNS: 16190

SIQ has audited the quality system in accordance with MDD Annex V and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on

Audit report No.:

OSV 01274/2018, 2018-11-28
OSV 01384/2018, 2019-01-15
OSV 01488/2018, 2019-01-31
OSV 00580/2019, 2019-05-31
OSV 00944/2019, 2019-08-22
OSV 01069A/2019, 2019-09-23

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4) and continues to meet the above requirements.

Certification date: 2019-10-10

Issue: 1/2019-10-10

Valid until: 2024-05-27



Director of SIQ

Igor Likar