EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-112

Issued to:	ADITEK do Brazil Ltda. Rua Cesário Motta, 14, Cravinhos, SP, BRASIL
Place of production:	ADITEK do Brazil Ltda. Rua Cesário Motta, 14, Cravinhos, SP, BRASIL
Product category:	Orthodontic Fixation System
GMDN:	46338, 31759, 46581,63379, 63223, 35439, 58818
Product category:	Orthodontic Wire
GMDN:	16204
Product category:	Orthodontic Spring
GMDN:	31797

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:
OSV 001273A/2018, 2019-01-10

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 II (5) and continues to meet the above requirements.

Certification date: 2018-12-12

Issue: 2/2019-01-10

Valid until: 2021-12-12

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