



EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. CE 693490
Issued To: TP Orthodontics Inc.
100 Center Plaza
LaPorte
Indiana
46350
USA

In respect of:

The manufacture of non-sterile orthodontic brackets, wires, ligatures, and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-12-23**

Date: **2019-12-23**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



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Supplementary Information to CE 693490

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NBOG Code(s)	Device Description	Intended purpose
Class IIa		
MD 0402	Orthodontic appliances and accessories	Treatment of dental malocclusion

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