

Production Quality Assurance
Directive 93/42/EEC on Medical devices, Annex V

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Savaria-Dent Kft.

Headquarters: **9700 Szombathely, Dr. Szabolcs Zoltán u. 5/A., HUNGARY**

Manufacturing plant: **9700 Szombathely, Vízöntő u. 9., HUNGARY**

Scope:

Orthodontic devices

The certificate covers the following devices:

Description of the device	Type	Intended use	Risk class
Orthodontic tube	Lingual Tube	orthodontics	II.a
Orthodontic hook	Lingual Cleats	orthodontics	II.a
Palatal arch	Goshgarian arches	orthodontics	II.a
Palatal arch	Quad Helix	orthodontics	II.a
Palatal arch	Bi Helix	orthodontics	II.a
Ligature	Pretwisted Ligature	orthodontics	II.a

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 35-CE-170104

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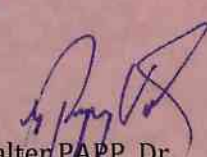
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