

DECLARATION OF CONFORMITY

We, **SAVARIA-DENT KFT.**
(name of manufacturer)

H-9700 Szombathely, Dr. Szabolcs Zoltán u. 5/A Cg. 18-09-100590
(headquarters and company registration number)

in our sole responsibility we declare that the products hereunder,

Orthodontic pliers

(name of products)

I.

(risk classification)

which this declaration relates to, conform with the content of 1st Appendix of 4/2009.(III.17.)

EÜM regulation and have the performance intended by the manufacturer. When used as intended, they do not endanger health and safety of the operator, patient or any other person.

They have been manufactured according to the requirements of standard ISO 13485:2003 Manufacturing takes place in ISO 9001:2008 Quality Management System, observing its requirements.

The product is manufactured in compliance with the actual Technical Documentation.

We have compiled the Technical Documentation according to the 7th Appendix of 4/2009 (III.17) EÜM regulation, keep it available and store it for five additional years after producing the last product and we provide it to

National Institute of Pharmacy and Nutrition upon their request for investigation.

We declare that the foregoing product is in compliance with the regulations of the 93/42 EEC Directive.

Place and address of storage of the Technical Documentation which this Declaration was based on:

Savaria-Dent Ltd.

H-9700 Szombathely, Dr. Szabolcs Zoltán 5/A

Szombathely, 02 January 2017

Place and date of Declaration

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András Gál, Manager

Name and position of representative