

DECLARATION OF CONFORMITY

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

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

in our sole responsibility we declare that the products hereunder,

Lingual Tube
Lingual Cleats
Goshgarian arches
Quad Helix
Bi Helix
Pretwisted Ligature
(name of products)
II a
(risk classification)

which this declaration relates to, conforms with the content of 1st Appendix of 4/2009.(III.17.) EÜM regulation and is manufactured in compliance with the requirements of ISO 13485:2003. Manufacturing takes place in ISO 9001:2008 Quality Management System, observing its requirements.

The products 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.

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

Evaluation of compliance took place with contribution of the Notified Body hereunder:
CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering
H-2040 Budaörs, Gyár u. 2.BITEP, Gábor Dénes krt. 101. HUNGARY
ID number: 2409

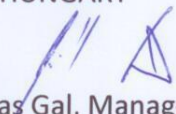
The products is provided with CE conformity mark.

Identification of the certificate to confirm this declaration, issued by the Notified Body:
EC Certificate No.: 144699-17-04-26
Expiration date: 25 April 2022

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

Savaria-Dent Ltd.
H-9700 Szombathely, Dr. Szabolcs Zoltán 5/A., HUNGARY

Szombathely, 26 April 2017
Place and date of Declaration


Andras Gal, Manager
Name and position of representative