



EU DECLARATION OF CONFORMITY

Product (trade) name:	Lingual Sheath
Product types:	1. Lingual Sheath Normal (Window) 2. Lingual Sheath Bridge 3. Lingual Sheath Curved 4. Lingual Sheath Wing (Right) 5. Lingual Sheath Wing (Left) 6. Lingual Sheath NoWindow
Size variants:	-
Catalog number:	According to the Attachment (<i>identifier</i> : DoC-EN-LT-MEL)
Basic UDI-DI: (acc. to MDR Annex VI Part C)	599953243011P2
Product description:	Orthodontic tube, medical device
Intended Purpose:	As part of an orthodontic appliance, for the alignment of teeth and the correction of jaw position and function, for aesthetic or medical reasons.
Name of manufacturer:	"SAVARIA-DENT" Fogászati Segédeszközt Gyártó és Kereskedelmi Korlátolt Felelősségű Társaság (English: "SAVARIA-DENT" Dental Devices Manufacturing and Trading Limited Liability Company) (<i>short name</i> : Savaria-Dent Ltd.)
Address of manufacturer:	9700 Szombathely, Dr. Szabolcs Z. u. 5/A. (Hungary)
Single Registration Number (SRN) of manufacturer:	SRN- HU-MF-000003421
Product legislation:	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Risk class: (acc. to MDR Annex VIII)	Ila
Description of the conformity assessment process:	Procedure according to Chapters I and III of Annex IX of the MDR, <i>supplemented by the procedure according to Chapter II of Annex IX of the MDR.</i>
Notified Body legal name:	CE Certiso Kft.
Address of the Notified Body:	2092 Budakeszi, Erdő u. 101. (Hungary)
Notified Body number:	NB 2409
Other references:	There are no applicable uniform standards for this device.

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Certificate Declaration - type:	EU Quality Management System Certificate Regulation (EU) 2017/745, Annex IX, Chapter I
- number:	145259-26-08-04
- validity:	03 August 2031
Additional information:	The device has no accessories. <i>The device does not contain:</i> - materials of animal origin, tissues, products with such content; - materials of human origin, tissues, products with such content; - human blood, blood derivatives or substances containing such; - phthalates or products with such content; - nanomaterials or products with such content; - medicinal substance or a preparation containing such a substance. The device may contain cobalt (<i>CMR material</i>) exceeding 0.1% by weight (m/m) due to the specifics of the manufacturing technology of the raw material. For data on the quality of the material of the device, see the declaration attachment (<i>identifier: DoC-EN-LT-MEL</i>)
Statements:	I declare that the <i>Lingual Sheath</i> device manufactured by me and identified in this declaration complies with the requirements of the MDR Regulation. I declare that this EU declaration of conformity is issued under the sole responsibility of Savaria-Dent Kft. Savaria-Dent Kft. designs and manufactures the <i>Lingual Sheath</i> device identified in this declaration in accordance with the requirements of the MSZ EN ISO 13485:2016 standard. This declaration is valid for all CE marked <i>Lingual Sheath</i> devices placed on the market after the date of issue of this declaration.

Place and date of issue of the EU declaration of conformity, countersignature:

Szombathely, August 5, 2026



 Gál András,
 managing director
person authorized to represent
 Savaria-Dent Kft.



EU DECLARATION OF CONFORMITY - ATTACHMENT

Product name	Basic UDI-DI	
Lingual Sheath	599953243011P2	
Article Code	Product trade name	UDI-DI code
SD 21-601 M	Lingual Sheath Normal (Window)	5999532430001
SD 21-600 BS	Lingual Sheath Bridge	5999532434115
SD 21-650 K	Lingual Sheath Curved	5999532433385
SD 21-601 A	Lingual Sheath Wing (Right)	5999532434122
SD 21-601 B	Lingual Sheath Wing (Left)	5999532434139
SD 21-601 T	Lingual Sheath NoWindow	5999532433392

The base material of the device	1.4301 stainless steel (X5CrNi18-10)							
Chemical composition of the base material	It complies with the requirements of the MSZ EN ISO 10088-2 standard (<i>Stainless steels. Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resistant steels for general purposes</i>)							
	C	Si	Mn	P	S	Cr	Ni	N
	max. 0,07	max. 1,0	max. 2,0	max. 0,045	max. 0,015	17,5 ~19,5	8,0~ 10,5	max 0,1
Other important physical characteristics	- Yield strength $R_{p0.2}$ [MPa]: ≥ 230 - Tensile strength R_m [MPa]: 540-750 - Elongation A [%]: ≥ 45							
Additional information	The device does not contain any absorbable or locally distributed materials. The device may contain cobalt (<i>CMR material</i>) exceeding 0.1% by weight (m/m) due to the specifics of the manufacturing technology of the raw material.							

Date: Szombathely, August 5, 2026


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Gál András
managing director
person authorized to represent
Savaria-Dent Kft.