

EU DECLARATION OF CONFORMITY

Product (trade) name:	Headcap	
Product types:	1. Headcap, narrow ear 2. Headcap, wide ear 3. Headcap, narrow ear (middle) 4. Jeans headcap, wide ear 5. Jeans headcap, narrow ear 6. Jeans headcap, round ear 7. Jeans headcap, narrow 5 ears	
Product size:	n.a.	
Product catalog or item number:	SD 48140 SD 48141 SD 48142 SD 48197 SD 48198 SD 48198-0 SD 48199	Headcap, narrow ear Headcap, wide ear Headcap, narrow ear (middle) Jeans headcap, wide ear Jeans headcap, narrow ear Jeans headcap, round ear Jeans headcap, narrow 5 ears
Basic UDI-DI: (acc. to MDR Annex VI. part C.)	599953243009PF	
Product description:	Sewn orthodontic devices, medical devices	
Product destination:	Orthodontic. The devices to be used during the orthodontics treatments.	
Name of manufacturer:	"SAVARIA-DENT" Dental Aids Manufacturing and Trading Limited Liability Company (in brief: Savaria-Dent Kft.)	
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 (April 5, 2017) on medical devices, amending Directive 2001/83/EC, Regulation 178/2002/EC and Regulation 1223/2009/EC, and repealing Council Directives 90/385/EEC and 93/42/EEC (in brief: MDR)	
Risk class: (acc. to MDR Annex VIII.)	Class I.	
Description of the conformity assessment process:	The compliance of our products with MDR II. and III. we confirm it with the technical documentation according to the annex.	
Name of Notified body:	n.a.	
Address of Notified body:	n.a.	
Identification number of Notified Body:	n.a.	
Other links:	n.a.	

EU DECLARATION OF CONFORMITY

Certificate supporting declaration	-
- type:	n.a.
- number:	n.a.
- validity:	n.a.
Additional information:	The device has no accessories. The device does not include: - 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; - carcinogenic, mutagenic, teratogenic (abbreviated: <i>CMR</i>) substances or products containing such substances; - phthalates or products with such content; - nanomaterials or products with such content; - medicinal substance or a preparation containing such a substance.
Statements:	I declare that the <i>Headcap</i> device manufactured by me and identified in this declaration meets the requirements of the MDR regulation. A 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>Headcap</i> device indentified in this statement in accordance with the requirements of the MSZ EN ISO 13485:2016 standard. This statement applies to all CE marked <i>Headcap</i> device that are placed on the market after the date of issue of this statement.

Place and date of issuance of the EU Declaration of Conformity, countersignature:

Szombathely, January 24, 2023.


Gál András
Managing Director
Person entitled to representativ
Savaria-Dent Kft.