

EU Declaration of Conformity

(Regulation 2017/745 (MDR), for medical device of Risk Class I)

1. Name of manufacturer: Savaria-Dent Kft.
2. Single Registration Number (SRN) of manufacturer: HU-MF-000003421
3. Address: 9700 Szombathely, Dr. Szabolcs Zoltán u. 5/A
4. This declaration of conformity was issued under the sole responsibility of my company, as manufacturers. Hereby I declare that the following product(s) that are manufactured by us

Product name: Neckpad, strap

Product's trade name: Neckpad, strap

Product codes:

SD 48160	Neckpad + strap, wide ear	SD 48167	Ear strap black
SD 48161	Strap jeans, narrow ear	SD 48170	Neckpad R + strap R, narrow ear
SD 48162	Strap, wide ear	SD 48171	Neckpad R + strap R, wide ear
SD 48162-L	Strap, wide ear L	SD 48173	Neckpad blue + strap pink, narrow ear
SD 48162-XL	Strap, wide ear XL	SD 48174	Neckpad blue + strap yellow, narrow ear
SD 48163	Strap, narrow ear	SD 48181	Jeans bunt, wide ear
SD 48163-L	Strap, narrow ear L	SD 48182	Jeans bunt, narrow ear
SD 48163-XL	Strap, narrow ear XL	SD 48186	Jeans bunt, jeans, narrow ear
SD 48164	Neckpad, buttonhole	SD 48187	Jeans bunt, jeans, wide ear
SD 48166	Ear strap blue		

Risk class: Class I.

Basic UDI-DI: 599953243010NY

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to the requirements stated in the EU Regulation 2017/745 on medical devices. The documents confirming this are available at the manufacturer.

Date: Szombathely, May 26, 2021.


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