

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: U Concept The Ultimate Bio Trainer
Product codes:

see Annex I.

Risk class: Class I.

Classification rule: According to Rule 5, 2nd indent of EU 2017/745 (MDR) Annex VIII
Basic UDI-DI: 599953243007PB

c o n f o r m

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

Dátum: Szombathely, May 26, 2021.


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

EU-Declaration of Conformity
U Concept The Ultimate Bio Trainer
Annex I.

<i>Reference number</i>	<i>Trade name</i>	<i>Reference number</i>	<i>Trade name</i>
SDUC2Pre-M-SR	U Class 2 Pre Mint Semi-rigid	SDUC3S-M-SR	U Class 3 Small Mint Semi-rigid
SDUC2Pre-G-SR	U Class 2 Pre Green Semi-rigid	SDUC3S-G-SR	U Class 3 Small Green Semi-rigid
SDUC2Pre-P-SR	U Class 2 Pre Pink Semi-rigid	SDUC3S-P-SR	U Class 3 Small Pink Semi-rigid
SDUC2Pre-Y-SR	U Class 2 Pre Yellow Semi-rigid	SDUC3S-Y-SR	U Class 3 Small Yellow Semi-rigid

SDUP1-TR-S	U Pilot 1 Transparent Soft	SDUP2-TR-S	U Pilot 2 Transparent Soft
SDUP1-LB-S	U Pilot 1 Lightblue Soft	SDUP2-LB-S	U Pilot 2 Lightblue Soft
SDUP1-DB-S	U Pilot 1 Darkblue Soft	SDUP2-DB-S	U Pilot 2 Darkblue Soft
SDUP1-TU-S	U Pilot 1 Turquoise Soft	SDUP2-TU-S	U Pilot 2 Turquoise Soft
SDUP1-R-S	U Pilot 1 Red Soft	SDUP2-R-S	U Pilot 2 Red Soft
SDUP1-M-S	U Pilot 1 Mint Soft	SDUP2-M-S	U Pilot 2 Mint Soft
SDUP1-G-S	U Pilot 1 Green Soft	SDUP2-G-S	U Pilot 2 Green Soft
SDUP1-P-S	U Pilot 1 Pink Soft	SDUP2-P-S	U Pilot 2 Pink Soft
SDUP1-Y-S	U Pilot 1 Yellow Soft	SDUP2-Y-S	U Pilot 2 Yellow Soft
SDUP1-TR-SR	U Pilot 1 Transparent Semi-rigid	SDUP2-TR-SR	U Pilot 2 Transparent Semi-rigid
SDUP1-LB-SR	U Pilot 1 Lightblue Semi-rigid	SDUP2-LB-SR	U Pilot 2 Lightblue Semi-rigid
SDUP1-DB-SR	U Pilot 1 Darkblue Semi-rigid	SDUP2-DB-SR	U Pilot 2 Darkblue Semi-rigid
SDUP1-TU-SR	U Pilot 1 Turquoise Semi-rigid	SDUP2-TU-SR	U Pilot 2 Turquoise Semi-rigid
SDUP1-R-SR	U Pilot 1 Red Semi-rigid	SDUP2-R-SR	U Pilot 2 Red Semi-rigid
SDUP1-M-SR	U Pilot 1 Mint Semi-rigid	SDUP2-M-SR	U Pilot 2 Mint Semi-rigid
SDUP1-G-SR	U Pilot 1 Green Semi-rigid	SDUP2-G-SR	U Pilot 2 Green Semi-rigid
SDUP1-P-SR	U Pilot 1 Pink Semi-rigid	SDUP2-P-SR	U Pilot 2 Pink Semi-rigid
SDUP2-Y-SR	U Pilot 1 Yellow Semi-rigid	SDUP2-Y-SR	U Pilot 2 Yellow Semi-rigid

SDUP3-TR-S	U Pilot 3 Transparent Soft	SDUP4-TR-S	U Pilot 4 Transparent Soft
SDUP3-LB-S	U Pilot 3 Lightblue Soft	SDUP4-LB-S	U Pilot 4 Lightblue Soft
SDUP3-DB-S	U Pilot 3 Darkblue Soft	SDUP4-DB-S	U Pilot 4 Darkblue Soft
SDUP3-TU-S	U Pilot 3 Turquoise Soft	SDUP4-TU-S	U Pilot 4 Turquoise Soft
SDUP3-R-S	U Pilot 3 Red Soft	SDUP4-R-S	U Pilot 4 Red Soft
SDUP3-M-S	U Pilot 3 Mint Soft	SDUP4-M-S	U Pilot 4 Mint Soft
SDUP3-G-S	U Pilot 3 Green Soft	SDUP4-G-S	U Pilot 4 Green Soft
SDUP3-P-S	U Pilot 3 Pink Soft	SDUP4-P-S	U Pilot 4 Pink Soft
SDUP3-Y-S	U Pilot 3 Yellow Soft	SDUP4-Y-S	U Pilot 4 Yellow Soft
SDUP3-TR-SR	U Pilot 3 Transparent Semi-rigid	SDUP4-TR-SR	U Pilot 4 Transparent Semi-rigid
SDUP3-LB-SR	U Pilot 3 Lightblue Semi-rigid	SDUP4-LB-SR	U Pilot 4 Lightblue Semi-rigid
SDUP3-DB-SR	U Pilot 3 Darkblue Semi-rigid	SDUP4-DB-SR	U Pilot 4 Darkblue Semi-rigid
SDUP3-TU-SR	U Pilot 3 Turquoise Semi-rigid	SDUP4-TU-SR	U Pilot 4 Turquoise Semi-rigid
SDUP3-R-SR	U Pilot 3 Red Semi-rigid	SDUP4-R-SR	U Pilot 4 Red Semi-rigid
SDUP3-M-SR	U Pilot 3 Mint Semi-rigid	SDUP4-M-SR	U Pilot 4 Mint Semi-rigid
SDUP3-G-SR	U Pilot 3 Green Semi-rigid	SDUP4-G-SR	U Pilot 4 Green Semi-rigid
SDUP3-P-SR	U Pilot 3 Pink Semi-rigid	SDUP4-P-SR	U Pilot 4 Pink Semi-rigid
SDUP3-Y-SR	U Pilot 3 Yellow Semi-rigid	SDUP4-Y-SR	U Pilot 4 Yellow Semi-rigid

SDUP5-TR-S	U Pilot 5 Transparent Soft	SDUP6-TR-S	U Pilot 6 Transparent Soft
SDUP5-LB-S	U Pilot 5 Lightblue Soft	SDUP6-LB-S	U Pilot 6 Lightblue Soft

EU-Declaration of Conformity
U Concept The Ultimate Bio Trainer
Annex I.

<i>Reference number</i>	<i>Trade name</i>	<i>Reference number</i>	<i>Trade name</i>
SDUK-TR-S	U Kiddy Transparent Soft	SDUT-TR-S	U Trainer Transparent Soft
SDUK-LB-S	U Kiddy Lightblue Soft	SDUT-LB-S	U Trainer Lightblue Soft
SDUK-DB-S	U Kiddy Darkblue Soft	SDUT-DB-S	U Trainer Darkblue Soft
SDUK-TU-S	U Kiddy Turquoise Soft	SDUT-TU-S	U Trainer Turquoise Soft
SDUK-R-S	U Kiddy Red Soft	SDUT-R-S	U Trainer Red Soft
SDUK-M-S	U Kiddy Mint Soft	SDUT-M-S	U Trainer Mint Soft
SDUK-G-S	U Kiddy Green Soft	SDUT-G-S	U Trainer Green Soft
SDUK-P-S	U Kiddy Pink Soft	SDUT-P-S	U Trainer Pink Soft
SDUK-Y-S	U Kiddy Yellow Soft	SDUT-Y-S	U Trainer Yellow Soft
SDUK-TR-SR	U Kiddy Transparent Semi-rigid	SDUT-TR-SR	U Trainer Transparent Semi-rigid
SDUK-LB-SR	U Kiddy Lightblue Semi-rigid	SDUT-LB-SR	U Trainer Lightblue Semi-rigid
SDUK-DB-SR	U Kiddy Darkblue Semi-rigid	SDUT-DB-SR	U Trainer Darkblue Semi-rigid
SDUK-TU-SR	U Kiddy Turquoise Semi-rigid	SDUT-TU-SR	U Trainer Turquoise Semi-rigid
SDUK-R-SR	U Kiddy Red Semi-rigid	SDUT-R-SR	U Trainer Red Semi-rigid
SDUK-M-SR	U Kiddy Mint Semi-rigid	SDUT-M-SR	U Trainer Mint Semi-rigid
SDUK-G-SR	U Kiddy Green Semi-rigid	SDUT-G-SR	U Trainer Green Semi-rigid
SDUK-P-SR	U Kiddy Pink Semi-rigid	SDUT-P-SR	U Trainer Pink Semi-rigid
SDUK-Y-SR	U Kiddy Yellow Semi-rigid	SDUT-Y-SR	U Trainer Yellow Semi-rigid
SDUS-TR-S	U Start Transparent Soft	SDUTS-TR-S	U Trainer Soft Transparent Soft
SDUS-LB-S	U Start Lightblue Soft	SDUTS-LB-S	U Trainer Soft Lightblue Soft
SDUS-DB-S	U Start Darkblue Soft	SDUTS-DB-S	U Trainer Soft Darkblue Soft
SDUS-TU-S	U Start Turquoise Soft	SDUTS-TU-S	U Trainer Soft Turquoise Soft
SDUS-R-S	U Start Red Soft	SDUTS-R-S	U Trainer Soft Red Soft
SDUS-M-S	U Start Mint Soft	SDUTS-M-S	U Trainer Soft Mint Soft
SDUS-G-S	U Start Green Soft	SDUTS-G-S	U Trainer Soft Green Soft
SDUS-P-S	U Start Pink Soft	SDUTS-P-S	U Trainer Soft Pink Soft
SDUS-Y-S	U Start Yellow Soft	SDUTS-Y-S	U Trainer Soft Yellow Soft
SDUS-TR-SR	U Start Transparent Semi-rigid	SDUTS-TR-SR	U Trainer Soft Transparent Semi-rigid
SDUS-LB-SR	U Start Lightblue Semi-rigid	SDUTS-LB-SR	U Trainer Soft Lightblue Semi-rigid
SDUS-DB-SR	U Start Darkblue Semi-rigid	SDUTS-DB-SR	U Trainer Soft Darkblue Semi-rigid
SDUS-TU-SR	U Start Turquoise Semi-rigid	SDUTS-TU-SR	U Trainer Soft Turquoise Semi-rigid
SDUS-R-SR	U Start Red Semi-rigid	SDUTS-R-SR	U Trainer Soft Piros Félkemény
SDUS-M-SR	U Start Mint Semi-rigid	SDUTS-M-SR	U Trainer Soft Mint Semi-rigid
SDUS-G-SR	U Start Green Semi-rigid	SDUTS-G-SR	U Trainer Soft Green Semi-rigid
SDUS-P-SR	U Start Pink Semi-rigid	SDUTS-P-SR	U Trainer Soft Pink Semi-rigid
SDUS-Y-SR	U Start Yellow Semi-rigid	SDUTS-Y-SR	U Trainer Soft Yellow Semi-rigid
SDUB-TR-S	U Brace Transparent Soft	SDUBS-TR-S	U Brace Small Transparent Soft
SDUB-LB-S	U Brace Lightblue Soft	SDUBS-LB-S	U Brace Small Lightblue Soft
SDUB-DB-S	U Brace Darkblue Soft	SDUBS-DB-S	U Brace Small Darkblue Soft
SDUB-TU-S	U Brace Turquoise Soft	SDUBS-TU-S	U Brace Small Turquoise Soft
SDUB-R-S	U Brace Red Soft	SDUBS-R-S	U Brace Small Red Soft
SDUB-M-S	U Brace Mint Soft	SDUBS-M-S	U Brace Small Mint Soft
SDUB-G-S	U Brace Green Soft	SDUBS-G-S	U Brace Small Green Soft

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SDUB-P-S	U Brace Pink Soft	SDUBS-P-S	U Brace Small Pink Soft
SDUB-Y-S	U Brace Yellow Soft	SDUBS-Y	U Brace Small Yellow Soft
SDUB-TR-SR	U Brace Transparent Semi-rigid	SDUBS-TR-SR	U Brace Small Transparent Semi-rigid
SDUB-LB-SR	U Brace Lightblue Semi-rigid	SDUBS-LB-SR	U Brace Small Lightblue Semi-rigid
SDUB-DB-SR	U Brace Darkblue Semi-rigid	SDUBS-DB-SR	U Brace Small Darkblue Semi-rigid
SDUB-TU-SR	U Brace Turquoise Semi-rigid	SDUBS-TU-SR	U Brace Small Turquoise Semi-rigid
SDUB-R-SR	U Brace Red Semi-rigid	SDUBS-R-SR	U Brace Small Red Semi-rigid
SDUB-M-SR	U Brace Mint Semi-rigid	SDUBS-M-SR	U Brace Small Mint Semi-rigid
SDUB-G-SR	U Brace Green Semi-rigid	SDUBS-G-SR	U Brace Small Green Semi-rigid
SDUB-P-SR	U Brace Pink Semi-rigid	SDUBS-P-SR	U Brace Small Pink Semi-rigid
SDUB-Y-SR	U Brace Yellow Semi-rigid	SDUBS-Y-SR	U Brace Small Yellow Semi-rigid

SDUC2-TR-S	U Class 2 Transparent Soft	SDUC3-TR-S	U Class 3 Transparent Soft
SDUC2-LB-S	U Class 2 Lightblue Soft	SDUC3-LB-S	U Class 3 Lightblue Soft
SDUC2-DB-S	U Class 2 Darkblue Soft	SDUC3-DB-S	U Class 3 Darkblue Soft
SDUC2-TU-S	U Class 2 Turquoise Soft	SDUC3-TU-S	U Class 3 Turquoise Soft
SDUC2-R-S	U Class 2 Red Soft	SDUC3-R-S	U Class 3 Red Soft
SDUC2-M-S	U Class 2 Mint Soft	SDUC3-M-S	U Class 3 Mint Soft
SDUC2-G-S	U Class 2 Green Soft	SDUC3-G-S	U Class 3 Green Soft
SDUC2-P-S	U Class 2 Pink Soft	SDUC3-P-S	U Class 3 Pink Soft
SDUC2-Y-S	U Class 2 Yellow Soft	SDUC3-Y-S	U Class 3 Yellow Soft
SDUC2-TR-SR	U Class 2 Transparent Semi-rigid	SDUC3-TR-SR	U Class 3 Transparent Semi-rigid
SDUC2-LB-SR	U Class 2 Lightblue Semi-rigid	SDUC3-DB-SR	U Class 3 Darkblue Semi-rigid
SDUC2-DB-SR	U Class 2 Darkblue Semi-rigid	SDUC3-LB-SR	U Class 3 Lightblue Semi-rigid
SDUC2-TU-SR	U Class 2 Turquoise Semi-rigid	SDUC3-TU-SR	U Class 3 Turquoise Semi-rigid
SDUC2-R-SR	U Class 2 Red Semi-rigid	SDUC3-R-SR	U Class 3 Piros Félkemény
SDUC2-M-SR	U Class 2 Mint Semi-rigid	SDUC3-M-SR	U Class 3 Mint Semi-rigid
SDUC2-G-SR	U Class 2 Green Semi-rigid	SDUC3-G-SR	U Class 3 Green Semi-rigid
SDUC2-P-SR	U Class 2 Pink Semi-rigid	SDUC3-P-SR	U Class 3 Pink Semi-rigid
SDUC2-Y-SR	U Class 2 Yellow Semi-rigid	SDUC3-Y-SR	U Class 3 Yellow Semi-rigid

SDUC2Pre-TR-S	U Class 2 Pre Transparent Soft	SDUC3S-TR-S	U Class 3 Small Transparent Soft
SDUC2Pre-LB-S	U Class 2 Pre Lightblue Soft	SDUC3S-LB-S	U Class 3 Small Lightblue Soft
SDUC2Pre-DB-S	U Class 2 Pre Darkblue Soft	SDUC3S-DB-S	U Class 3 Small Darkblue Soft
SDUC2Pre-TU-S	U Class 2 Pre Turquoise Soft	SDUC3S-TU-S	U Class 3 Small Turquoise Soft
SDUC2Pre-R-S	U Class 2 Pre Red Soft	SDUC3S-R-S	U Class 3 Small Red Soft
SDUC2Pre-M-S	U Class 2 Pre Mint Soft	SDUC3S-M-S	U Class 3 Small Mint Soft
SDUC2Pre-G-S	U Class 2 Pre Green Soft	SDUC3S-G-S	U Class 3 Small Green Soft
SDUC2Pre-P-S	U Class 2 Pre Pink Soft	SDUC3S-P-S	U Class 3 Small Pink Soft
SDUC2Pre-Y-S	U Class 2 Pre Yellow Soft	SDUC3S-Y-S	U Class 3 Small Yellow Soft
SDUC2Pre-TR-SR	U Class 2 Pre Transparent Semi-rigid	SDUC3S-TR-SR	U Class 3 Small Transparent Semi-rigid
SDUC2Pre-LB-SR	U Class 2 Pre Lightblue Semi-rigid	SDUC3S-LB-SR	U Class 3 Small Lightblue Semi-rigid
SDUC2Pre-DB-SR	U Class 2 Pre Darkblue Semi-rigid	SDUC3S-DB-SR	U Class 3 Small Darkblue Semi-rigid
SDUC2Pre-TU-SR	U Class 2 Pre Turquoise Semi-rigid	SDUC3S-TU-SR	U Class 3 Small Turquoise Semi-rigid
SDUC2Pre-R-SR	U Class 2 Pre Red Semi-rigid	SDUC3S-R-SR	U Class 3 Small Red Semi-rigid

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Reference number	Trade name	Reference number	Trade name
SDUP5-DB-S	U Pilot 5 Darkblue Soft	SDUP6-DB-S	U Pilot 6 Darkblue Soft
SDUP5-TU-S	U Pilot 5 Turquoise Soft	SDUP6-TU-S	U Pilot 6 Turquoise Soft
SDUP5-R-S	U Pilot 5 Red Soft	SDUP6-R-S	U Pilot 6 Red Soft
SDUP5-M-S	U Pilot 5 Mint Soft	SDUP6-M-S	U Pilot 6 Mint Soft
SDUP5-G-S	U Pilot 5 Green Soft	SDUP6-G-S	U Pilot 6 Green Soft
SDUP5-P-S	U Pilot 5 Pink Soft	SDUP6-P-S	U Pilot 6 Pink Soft
SDUP5-Y-S	U Pilot 5 Yellow Soft	SDUP6-Y-S	U Pilot 6 Yellow Soft
SDUP5-TR-SR	U Pilot 5 Transparent Semi-rigid	SDUP6-TR-SR	U Pilot 6 Transparent Semi-rigid
SDUP5-LB-SR	U Pilot 5 Lightblue Semi-rigid	SDUP6-LB-SR	U Pilot 6 Lightblue Semi-rigid
SDUP5-DB-SR	U Pilot 5 Darkblue Semi-rigid	SDUP6-DB-SR	U Pilot 6 Darkblue Semi-rigid
SDUP5-TU-SR	U Pilot 5 Turquoise Semi-rigid	SDUP6-TU-SR	U Pilot 6 Turquoise Semi-rigid
SDUP5-R-SR	U Pilot 5 Red Semi-rigid	SDUP6-R-SR	U Pilot 6 Red Semi-rigid
SDUP5-M-SR	U Pilot 5 Mint Semi-rigid	SDUP6-M-SR	U Pilot 6 Mint Semi-rigid
SDUP5-G-SR	U Pilot 5 Green Semi-rigid	SDUP6-G-SR	U Pilot 6 Green Semi-rigid
SDUP5-P-SR	U Pilot 5 Pink Semi-rigid	SDUP6-P-SR	U Pilot 6 Pink Semi-rigid
SDUP5-Y-SR	U Pilot 5 Yellow Semi-rigid	SDUP6-Y-SR	U Pilot 6 Yellow Semi-rigid

SDUP7-TR-S	U Pilot 7 Transparent Soft	SDUTEMP1	U Template 1
SDUP7-LB-S	U Pilot 7 Lightblue Soft	SDUTEMP2	U Template 2
SDUP7-DB-S	U Pilot 7 Darkblue Soft	SDUTEMP3	U Template 3
SDUP7-TU-S	U Pilot 7 Turquoise Soft	SDUTEMP4	U Template 4
SDUP7-R-S	U Pilot 7 Red Soft	SDUTEMP5	U Template 5
SDUP7-M-S	U Pilot 7 Mint Soft	SDUTEMP6	U Template 6
SDUP7-G-S	U Pilot 7 Green Soft	SDUTEMP7	U Template 7
SDUP7-P-S	U Pilot 7 Pink Soft		
SDUP7-Y-S	U Pilot 7 Yellow Soft		
SDUP7-TR-SR	U Pilot 7 Transparent Semi-rigid		
SDUP7-LB-SR	U Pilot 7 Lightblue Semi-rigid		
SDUP7-DB-SR	U Pilot 7 Darkblue Semi-rigid		
SDUP7-TU-SR	U Pilot 7 Turquoise Semi-rigid		
SDUP7-R-SR	U Pilot 7 Red Semi-rigid		
SDUP7-M-SR	U Pilot 7 Mint Semi-rigid		
SDUP7-G-SR	U Pilot 7 Green Semi-rigid		
SDUP7-P-SR	U Pilot 7 Pink Semi-rigid		
SDUP7-Y-SR	U Pilot 7 Yellow Semi-rigid		