

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.

Date: 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.

Reference number	Trade name
SDUK-TR-S	U Kiddy Transparent Soft
SDUK-LB-S	U Kiddy Light Blue Soft
SDUK-DB-S	U Kiddy Dark Blue Soft
SDUK-TU-S	U Kiddy Turquoise Soft
SDUK-R-S	U Kiddy Red Soft
SDUK-M-S	U Kiddy Mint Soft
SDUK-G-S	U Kiddy Green Soft
SDUK-P-S	U Kiddy Pink Soft
SDUK-Y-S	U Kiddy Yellow Soft
SDUK-TR-SR	U Kiddy Transparent Semi-Rigid
SDUK-LB-SR	U Kiddy Light Blue Semi-Rigid
SDUK-DB-SR	U Kiddy Dark Blue Semi-Rigid
SDUK-TU-SR	U Kiddy Turquoise Semi-Rigid
SDUK-R-SR	U Kiddy Red Semi-Rigid
SDUK-M-SR	U Kiddy Mint Semi-Rigid
SDUK-G-SR	U Kiddy Green Semi-Rigid
SDUK-P-SR	U Kiddy Pink Semi-Rigid
SDUK-Y-SR	U Kiddy Yellow Semi-Rigid

Reference number	Trade name
SDUT-TR-S	U Trainer Transparent Soft
SDUT-LB-S	U Trainer Light Blue Soft
SDUT-DB-S	U Trainer Dark Blue Soft
SDUT-TU-S	U Trainer Turquoise Soft
SDUT-R-S	U Trainer Red Soft
SDUT-M-S	U Trainer Mint Soft
SDUT-G-S	U Trainer Green Soft
SDUT-P-S	U Trainer Pink Soft
SDUT-Y-S	U Trainer Yellow Soft
SDUT-TR-SR	U Trainer Transparent Semi-Rigid
SDUT-LB-SR	U Trainer Light Blue Semi-Rigid
SDUT-DB-SR	U Trainer Dark Blue Semi-Rigid
SDUT-TU-SR	U Trainer Turquoise Semi-Rigid
SDUT-R-SR	U Trainer Red Semi-Rigid
SDUT-M-SR	U Trainer Mint Semi-Rigid
SDUT-G-SR	U Trainer Green Semi-Rigid
SDUT-P-SR	U Trainer Pink Semi-Rigid
SDUT-Y-SR	U Trainer Yellow Semi-Rigid

SDUS-TR-S	U Start Transparent Soft
SDUS-LB-S	U Start Light Blue Soft
SDUS-DB-S	U Start Dark Blue Soft
SDUS-TU-S	U Start Turquoise Soft
SDUS-R-S	U Start Red Soft
SDUS-M-S	U Start Mint Soft
SDUS-G-S	U Start Green Soft
SDUS-P-S	U Start Pink Soft
SDUS-Y-S	U Start Yellow Soft
SDUS-TR-SR	U Start Transparent Semi-Rigid
SDUS-LB-SR	U Start Light Blue Semi-Rigid
SDUS-DB-SR	U Start Dark Blue Semi-Rigid
SDUS-TU-SR	U Start Turquoise Semi-Rigid
SDUS-R-SR	U Start Red Semi-Rigid
SDUS-M-SR	U Start Mint Semi-Rigid
SDUS-G-SR	U Start Green Semi-Rigid
SDUS-P-SR	U Start Pink Semi-Rigid
SDUS-Y-SR	U Start Yellow Semi-Rigid

SDUTS-TR-S	U Trainer S Transparent Soft
SDUTS-LB-S	U Trainer S Light Blue Soft
SDUTS-DB-S	U Trainer S Dark Blue Soft
SDUTS-TU-S	U Trainer S Turquoise Soft
SDUTS-R-S	U Trainer S Red Soft
SDUTS-M-S	U Trainer S Mint Soft
SDUTS-G-S	U Trainer S Green Soft
SDUTS-P-S	U Trainer S Pink Soft
SDUTS-Y-S	U Trainer S Yellow Soft
SDUTS-TR-SR	U Trainer S Transparent Semi-Rigid
SDUTS-LB-SR	U Trainer S Light Blue Semi-Rigid
SDUTS-DB-SR	U Trainer S Dark Blue Semi-Rigid
SDUTS-TU-SR	U Trainer S Turquoise Semi-Rigid
SDUTS-R-SR	U Trainer S Red Semi-Rigid
SDUTS-M-SR	U Trainer S Mint Semi-Rigid
SDUTS-G-SR	U Trainer S Green Semi-Rigid
SDUTS-P-SR	U Trainer S Pink Semi-Rigid
SDUTS-Y-SR	U Trainer S Yellow Semi-Rigid

SDUB-TR-S	U Brace Transparent Soft
SDUB-LB-S	U Brace Light Blue Soft
SDUB-DB-S	U Brace Dark Blue Soft
SDUB-TU-S	U Brace Turquoise Soft
SDUB-R-S	U Brace Red Soft
SDUB-M-S	U Brace Mint Soft
SDUB-G-S	U Brace Green Soft

SDUBS-TR-S	U Brace Small Transparent Soft
SDUBS-LB-S	U Brace Small Light Blue Soft
SDUBS-DB-S	U Brace Small Dark Blue Soft
SDUBS-TU-S	U Brace Small Turquoise Soft
SDUBS-R-S	U Brace Small Red Soft
SDUBS-M-S	U Brace Small Mint Soft
SDUBS-G-S	U Brace Small Green Soft

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Reference number	Trade name
SDUB-P-S	U Brace Pink Soft
SDUB-Y-S	U Brace Yellow Soft
SDUB-TR-SR	U Brace Transparent Semi-Rigid
SDUB-LB-SR	U Brace Light Blue Semi-Rigid
SDUB-DB-SR	U Brace Dark Blue Semi-Rigid
SDUB-TU-SR	U Brace Turquoise Semi-Rigid
SDUB-R-SR	U Brace Red Semi-Rigid
SDUB-M-SR	U Brace Mint Semi-Rigid
SDUB-G-SR	U Brace Green Semi-Rigid
SDUB-P-SR	U Brace Pink Semi-Rigid
SDUB-Y-SR	U Brace Yellow Semi-Rigid

Reference number	Trade name
SDUBS-P-S	U Brace Small Pink Soft
SDUBS-Y	U Brace Small Yellow Soft
SDUBS-TR-SR	U Brace Small Transparent Semi-Rigid
SDUBS-LB-SR	U Brace Small Light Blue Semi-Rigid
SDUBS-DB-SR	U Brace Small Dark Blue Semi-Rigid
SDUBS-TU-SR	U Brace Small Turquoise Semi-Rigid
SDUBS-R-SR	U Brace Small Red Semi-Rigid
SDUBS-M-SR	U Brace Small Mint Semi-Rigid
SDUBS-G-SR	U Brace Small Green Semi-Rigid
SDUBS-P-SR	U Brace Small Pink Semi-Rigid
SDUBS-Y-SR	U Brace Small Yellow Semi-Rigid

SDUC2-TR-S	U Class 2 Transparent Soft
SDUC2-LB-S	U Class 2 Light Blue Soft
SDUC2-DB-S	U Class 2 Dark Blue Soft
SDUC2-TU-S	U Class 2 Turquoise Soft
SDUC2-R-S	U Class 2 Red Soft
SDUC2-M-S	U Class 2 Mint Soft
SDUC2-G-S	U Class 2 Green Soft
SDUC2-P-S	U Class 2 Pink Soft
SDUC2-Y-S	U Class 2 Yellow Soft
SDUC2-TR-SR	U Class 2 Transparent Semi-Rigid
SDUC2-LB-SR	U Class 2 Light Blue Semi-Rigid
SDUC2-DB-SR	U Class 2 Dark Blue Semi-Rigid
SDUC2-TU-SR	U Class 2 Turquoise Semi-Rigid
SDUC2-R-SR	U Class 2 Red Semi-Rigid
SDUC2-M-SR	U Class 2 Mint Semi-Rigid
SDUC2-G-SR	U Class 2 Green Semi-Rigid
SDUC2-P-SR	U Class 2 Pink Semi-Rigid
SDUC2-Y-SR	U Class 2 Yellow Semi-Rigid

SDUC3-TR-S	U Class 3 Transparent Soft
SDUC3-LB-S	U Class 3 Light Blue Soft
SDUC3-DB-S	U Class 3 Dark Blue Soft
SDUC3-TU-S	U Class 3 Turquoise Soft
SDUC3-R-S	U Class 3 Red Soft
SDUC3-M-S	U Class 3 Mint Soft
SDUC3-G-S	U Class 3 Green Soft
SDUC3-P-S	U Class 3 Pink Soft
SDUC3-Y-S	U Class 3 Yellow Soft
SDUC3-TR-SR	U Class 3 Transparent Semi-Rigid
SDUC3-DB-SR	U Class 3 Dark Blue Semi-Rigid
SDUC3-LB-SR	U Class 3 Light Blue Semi-Rigid
SDUC3-TU-SR	U Class 3 Turquoise Semi-Rigid
SDUC3-R-SR	U Class 3 Red Semi-Rigid
SDUC3-M-SR	U Class 3 Mint Semi-Rigid
SDUC3-G-SR	U Class 3 Green Semi-Rigid
SDUC3-P-SR	U Class 3 Pink Semi-Rigid
SDUC3-Y-SR	U Class 3 Yellow Semi-Rigid

SDUC2Pre-TR-S	U Class 2 Pre Transparent Soft
SDUC2Pre-LB-S	U Class 2 Pre Light Blue Soft
SDUC2Pre-DB-S	U Class 2 Pre Dark Blue Soft
SDUC2Pre-TU-S	U Class 2 Pre Turquoise Soft
SDUC2Pre-R-S	U Class 2 Pre Red Soft
SDUC2Pre-M-S	U Class 2 Pre Mint Soft
SDUC2Pre-G-S	U Class 2 Pre Green Soft
SDUC2Pre-P-S	U Class 2 Pre Pink Soft
SDUC2Pre-Y-S	U Class 2 Pre Yellow Soft
SDUC2Pre-TR-SR	U Class 2 Pre Transparent Semi-Rigid
SDUC2Pre-LB-SR	U Class 2 Pre Light Blue Semi-Rigid
SDUC2Pre-DB-SR	U Class 2 Pre Dark Blue Semi-Rigid
SDUC2Pre-TU-SR	U Class 2 Pre Turquoise Semi-Rigid
SDUC2Pre-R-SR	U Class 2 Pre Red Semi-Rigid

SDUC3S-TR-S	U Class 3 Small Transparent Soft
SDUC3S-LB-S	U Class 3 Small Light Blue Soft
SDUC3S-DB-S	U Class 3 Small Dark Blue Soft
SDUC3S-TU-S	U Class 3 Small Turquoise Soft
SDUC3S-R-S	U Class 3 Small Red Soft
SDUC3S-M-S	U Class 3 Small Mint Soft
SDUC3S-G-S	U Class 3 Small Green Soft
SDUC3S-P-S	U Class 3 Small Pink Soft
SDUC3S-Y-S	U Class 3 Small Yellow Soft
SDUC3S-TR-SR	U Class 3 Small Transparent Semi-Rigid
SDUC3S-LB-SR	U Class 3 Small Light Blue Semi-Rigid
SDUC3S-DB-SR	U Class 3 Small Dark Blue Semi-Rigid
SDUC3S-TU-SR	U Class 3 Small Turquoise Semi-Rigid
SDUC3S-R-SR	U Class 3 Small Red Semi-Rigid

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Reference number	Trade name
SDUC2Pre-M-SR	U Class 2 Pre Mint Semi-Rigid
SDUC2Pre-G-SR	U Class 2 Pre Green Semi-Rigid
SDUC2Pre-P-SR	U Class 2 Pre Pink Semi-Rigid
SDUC2Pre-Y-SR	U Class 2 Pre Yellow Semi-Rigid

Reference number	Trade name
SDUC3S-M-SR	U Class 3 Small Mint Semi-Rigid
SDUC3S-G-SR	U Class 3 Small Green Semi-Rigid
SDUC3S-P-SR	U Class 3 Small Pink Semi-Rigid
SDUC3S-Y-SR	U Class 3 Small Yellow Semi-Rigid

SDUP1-TR-S	U Pilot 1 Transparent Soft
SDUP1-LB-S	U Pilot 1 Light Blue Soft
SDUP1-DB-S	U Pilot 1 Dark Blue Soft
SDUP1-TU-S	U Pilot 1 Turquoise Soft
SDUP1-R-S	U Pilot 1 Red Soft
SDUP1-M-S	U Pilot 1 Mint Soft
SDUP1-G-S	U Pilot 1 Green Soft
SDUP1-P-S	U Pilot 1 Pink Soft
SDUP1-Y-S	U Pilot 1 Yellow Soft
SDUP1-TR-SR	U Pilot 1 Transparent Semi-Rigid
SDUP1-LB-SR	U Pilot 1 Light Blue Semi-Rigid
SDUP1-DB-SR	U Pilot 1 Dark Blue Semi-Rigid
SDUP1-TU-SR	U Pilot 1 Turquoise Semi-Rigid
SDUP1-R-SR	U Pilot 1 Red Semi-Rigid
SDUP1-M-SR	U Pilot 1 Mint Semi-Rigid
SDUP1-G-SR	U Pilot 1 Green Semi-Rigid
SDUP1-P-SR	U Pilot 1 Pink Semi-Rigid
SDUP2-Y-SR	U Pilot 1 Yellow Semi-Rigid

SDUP2-TR-S	U Pilot 2 Transparent Soft
SDUP2-LB-S	U Pilot 2 Light Blue Soft
SDUP2-DB-S	U Pilot 2 Dark Blue Soft
SDUP2-TU-S	U Pilot 2 Turquoise Soft
SDUP2-R-S	U Pilot 2 Red Soft
SDUP2-M-S	U Pilot 2 Mint Soft
SDUP2-G-S	U Pilot 2 Green Soft
SDUP2-P-S	U Pilot 2 Pink Soft
SDUP2-Y-S	U Pilot 2 Yellow Soft
SDUP2-TR-SR	U Pilot 2 Transparent Semi-Rigid
SDUP2-LB-SR	U Pilot 2 Light Blue Semi-Rigid
SDUP2-DB-SR	U Pilot 2 Dark Blue Semi-Rigid
SDUP2-TU-SR	U Pilot 2 Turquoise Semi-Rigid
SDUP2-R-SR	U Pilot 2 Red Semi-Rigid
SDUP2-M-SR	U Pilot 2 Mint Semi-Rigid
SDUP2-G-SR	U Pilot 2 Green Semi-Rigid
SDUP2-P-SR	U Pilot 2 Pink Semi-Rigid
SDUP2-Y-SR	U Pilot 2 Yellow Semi-Rigid

SDUP3-TR-S	U Pilot 3 Transparent Soft
SDUP3-LB-S	U Pilot 3 Light Blue Soft
SDUP3-DB-S	U Pilot 3 Dark Blue Soft
SDUP3-TU-S	U Pilot 3 Turquoise Soft
SDUP3-R-S	U Pilot 3 Red Soft
SDUP3-M-S	U Pilot 3 Mint Soft
SDUP3-G-S	U Pilot 3 Green Soft
SDUP3-P-S	U Pilot 3 Pink Soft
SDUP3-Y-S	U Pilot 3 Yellow Soft
SDUP3-TR-SR	U Pilot 3 Transparent Semi-Rigid
SDUP3-LB-SR	U Pilot 3 Light Blue Semi-Rigid
SDUP3-DB-SR	U Pilot 3 Dark Blue Semi-Rigid
SDUP3-TU-SR	U Pilot 3 Turquoise Semi-Rigid
SDUP3-R-SR	U Pilot 3 Red Semi-Rigid
SDUP3-M-SR	U Pilot 3 Mint Semi-Rigid
SDUP3-G-SR	U Pilot 3 Green Semi-Rigid
SDUP3-P-SR	U Pilot 3 Pink Semi-Rigid
SDUP3-Y-SR	U Pilot 3 Yellow Semi-Rigid

SDUP4-TR-S	U Pilot 4 Transparent Soft
SDUP4-LB-S	U Pilot 4 Light Blue Soft
SDUP4-DB-S	U Pilot 4 Dark Blue Soft
SDUP4-TU-S	U Pilot 4 Turquoise Soft
SDUP4-R-S	U Pilot 4 Red Soft
SDUP4-M-S	U Pilot 4 Mint Soft
SDUP4-G-S	U Pilot 4 Green Soft
SDUP4-P-S	U Pilot 4 Pink Soft
SDUP4-Y-S	U Pilot 4 Yellow Soft
SDUP4-TR-SR	U Pilot 4 Transparent Semi-Rigid
SDUP4-LB-SR	U Pilot 4 Light Blue Semi-Rigid
SDUP4-DB-SR	U Pilot 4 Dark Blue Semi-Rigid
SDUP4-TU-SR	U Pilot 4 Turquoise Semi-Rigid
SDUP4-R-SR	U Pilot 4 Red Semi-Rigid
SDUP4-M-SR	U Pilot 4 Mint Semi-Rigid
SDUP4-G-SR	U Pilot 4 Green Semi-Rigid
SDUP4-P-SR	U Pilot 4 Pink Semi-Rigid
SDUP4-Y-SR	U Pilot 4 Yellow Semi-Rigid

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Reference number	Trade name
SDUP5-TR-S	U Pilot 5 Transparent Soft
SDUP5-LB-S	U Pilot 5 Light Blue Soft
SDUP5-DB-S	U Pilot 5 Dark Blue Soft
SDUP5-TU-S	U Pilot 5 Turquoise Soft
SDUP5-R-S	U Pilot 5 Red Soft
SDUP5-M-S	U Pilot 5 Mint Soft
SDUP5-G-S	U Pilot 5 Green Soft
SDUP5-P-S	U Pilot 5 Pink Soft
SDUP5-Y-S	U Pilot 5 Yellow Soft
SDUP5-TR-SR	U Pilot 5 Transparent Semi-Rigid
SDUP5-LB-SR	U Pilot 5 Light Blue Semi-Rigid
SDUP5-DB-SR	U Pilot 5 Dark Blue Semi-Rigid
SDUP5-TU-SR	U Pilot 5 Turquoise Semi-Rigid
SDUP5-R-SR	U Pilot 5 Red Semi-Rigid
SDUP5-M-SR	U Pilot 5 Mint Semi-Rigid
SDUP5-G-SR	U Pilot 5 Green Semi-Rigid
SDUP5-P-SR	U Pilot 5 Pink Semi-Rigid
SDUP5-Y-SR	U Pilot 5 Yellow Semi-Rigid

Reference number	Trade name
SDUP6-TR-S	U Pilot 6 Transparent Soft
SDUP6-LB-S	U Pilot 6 Light Blue Soft
SDUP6-DB-S	U Pilot 6 Dark Blue Soft
SDUP6-TU-S	U Pilot 6 Turquoise Soft
SDUP6-R-S	U Pilot 6 Red Soft
SDUP6-M-S	U Pilot 6 Mint Soft
SDUP6-G-S	U Pilot 6 Green Soft
SDUP6-P-S	U Pilot 6 Pink Soft
SDUP6-Y-S	U Pilot 6 Yellow Soft
SDUP6-TR-SR	U Pilot 6 Transparent Semi-Rigid
SDUP6-LB-SR	U Pilot 6 Light Blue Semi-Rigid
SDUP6-DB-SR	U Pilot 6 Dark Blue Semi-Rigid
SDUP6-TU-SR	U Pilot 6 Turquoise Semi-Rigid
SDUP6-R-SR	U Pilot 6 Red Semi-Rigid
SDUP6-M-SR	U Pilot 6 Mint Semi-Rigid
SDUP6-G-SR	U Pilot 6 Green Semi-Rigid
SDUP6-P-SR	U Pilot 6 Pink Semi-Rigid
SDUP6-Y-SR	U Pilot 6 Yellow Semi-Rigid

SDUP7-TR-S	U Pilot 7 Transparent Soft
SDUP7-LB-S	U Pilot 7 Light Blue Soft
SDUP7-DB-S	U Pilot 7 Dark Blue Soft
SDUP7-TU-S	U Pilot 7 Turquoise Soft
SDUP7-R-S	U Pilot 7 Red Soft
SDUP7-M-S	U Pilot 7 Mint Soft
SDUP7-G-S	U Pilot 7 Green Soft
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 Light Blue Semi-Rigid
SDUP7-DB-SR	U Pilot 7 Dark Blue 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

SDUTEMP1	U Template 1
SDUTEMP2	U Template 2
SDUTEMP3	U Template 3
SDUTEMP4	U Template 4
SDUTEMP5	U Template 5
SDUTEMP6	U Template 6
SDUTEMP7	U Template 7

SDUTP-TR-S	U Trainer Plus Transparent Soft
SDUTP-LB-S	U Trainer Plus Light Blue Soft
SDUTP-DB-S	U Trainer Plus Dark Blue Soft
SDUTP-P-S	U Trainer Plus Pink Soft
SDUTP-TR-SR	U Trainer Plus Transparent Semi-Rigid
SDUTP-LB-SR	U Trainer Plus Light Blue Semi-Rigid
SDUTP-DB-SR	U Trainer Plus Dark Blue Semi-Rigid
SDUPT-P-SR	U Trainer Plus Pink Semi-Rigid