SHINHUNG

Shinhung Building, 450, Cheongpa-ro, Jung-gu, Seoul, 04510 Korea

EC Declaration of Conformity

Manufacturer : Shinhung Co., Ltd.

Head Office: Shinhung Building, 450, Cheongpa-ro, Jung-gu, Seoul, 04510 Korea

Factory: 42-25, Dongsan-ro 27beon-gil, Danwon-gu, Ansan-si, Gyeong gi-do, 15433 Korea

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European Representative : CE Medical

Amerlandseweg 7, 3621 ZC Breukelen, The Netherlands

EC Certificate: CE 1639

EC Certificate number: KR19/81826324

Product : Preformed Crown

Model : KIDS CROWN series(Export Name for U.S.A. : PEDO CROWNS)

Upper D-Type		Lower D-Type	
Left	KIDS CROWN D-UL-2 KIDS CROWN D-UL-3 KIDS CROWN D-UL-4 KIDS CROWN D-UL-5 KIDS CROWN D-UL-6 KIDS CROWN D-UL-7	Left	KIDS CROWN D-LL-2 KIDS CROWN D-LL-3 KIDS CROWN D-LL-4 KIDS CROWN D-LL-5 KIDS CROWN D-LL-6 KIDS CROWN D-LL-7
Right	KIDS CROWN D-UR-2 KIDS CROWN D-UR-3 KIDS CROWN D-UR-4 KIDS CROWN D-UR-5 KIDS CROWN D-UR-6 KIDS CROWN D-UR-7	Right	KIDS CROWN D-LR-2 KIDS CROWN D-LR-3 KIDS CROWN D-LR-4 KIDS CROWN D-LR-5 KIDS CROWN D-LR-6 KIDS CROWN D-LR-7
Upper E-Type		Lower E-Type	
Left	KIDS CROWN E-UL-2 KIDS CROWN E-UL-3 KIDS CROWN E-UL-4 KIDS CROWN E-UL-5 KIDS CROWN E-UL-6 KIDS CROWN E-UL-7	Left	KIDS CROWN E-LL-2 KIDS CROWN E-LL-3 KIDS CROWN E-LL-4 KIDS CROWN E-LL-5 KIDS CROWN E-LL-6 KIDS CROWN E-LL-7
Right	KIDS CROWN E-UR-2 KIDS CROWN E-UR-3 KIDS CROWN E-UR-4 KIDS CROWN E-UR-5 KIDS CROWN E-UR-6 KIDS CROWN E-UR-7	Right	KIDS CROWN E-LR-2 KIDS CROWN E-LR-3 KIDS CROWN E-LR-4 KIDS CROWN E-LR-5 KIDS CROWN E-LR-6 KIDS CROWN E-LR-7

A-Type		B-Type	
Left	KIDS CROWN A-L-1, KIDS CROWN A-L-2 KIDS CROWN A-L-3, KIDS CROWN A-L-4 KIDS CROWN A-L-5, KIDS CROWN A-L-6	Left	KIDS CROWN B-L-1, KIDS CROWN B-L-2 KIDS CROWN B-L-3, KIDS CROWN B-L-4 KIDS CROWN B-L-5, KIDS CROWN B-L-6
Right	KIDS CROWN A-R-1, KIDS CROWN A-R-2 KIDS CROWN A-R-3, KIDS CROWN A-R-4 KIDS CROWN A-R-5, KIDS CROWN A-R-6	Right	KIDS CROWN B-R-1, KIDS CROWN B-R-2 KIDS CROWN B-R-3, KIDS CROWN B-R-4 KIDS CROWN B-R-5, KIDS CROWN B-R-6
C-Type			
Upper	KIDS CROWN C-U-1, KIDS CROWN C-U-2 KIDS CROWN C-U-3, KIDS CROWN C-U-4 KIDS CROWN C-U-5, KIDS CROWN C-U-6	Lower	KIDS CROWN C-L-1, KIDS CROWN C-L-2 KIDS CROWN C-L-3, KIDS CROWN C-L-4 KIDS CROWN C-L-5, KIDS CROWN C-L-6
PRIMARY MOLAR CROWN INTRO KIT (48 CROWNS) PRIMARY MOLAR CROWN INTRO KIT (96 CROWNS) PRIMARY ANTERIOR CROWN INTRO KIT (36 CROWNS) PRIMARY ANTERIOR CROWN INTRO KIT (72 CROWNS)			

Model : PEDO CROWNS series

Upper D-Type		Lower D-Type	
Left	PEDO CROWNS SSC-ULD2-CE PEDO CROWNS SSC-ULD3-CE PEDO CROWNS SSC-ULD4-CE PEDO CROWNS SSC-ULD5-CE PEDO CROWNS SSC-ULD6-CE PEDO CROWNS SSC-ULD7-CE	Left	PEDO CROWNS SSC-LLD2-CE PEDO CROWNS SSC-LLD3-CE PEDO CROWNS SSC-LLD4-CE PEDO CROWNS SSC-LLD5-CE PEDO CROWNS SSC-LLD6-CE PEDO CROWNS SSC-LLD7-CE
Right	PEDO CROWNS SSC-URD2-CE PEDO CROWNS SSC-URD3-CE PEDO CROWNS SSC-URD4-CE PEDO CROWNS SSC-URD5-CE PEDO CROWNS SSC-URD6-CE PEDO CROWNS SSC-URD7-CE	Right	PEDO CROWNS SSC-LRD2-CE PEDO CROWNS SSC-LRD3-CE PEDO CROWNS SSC-LRD4-CE PEDO CROWNS SSC-LRD5-CE PEDO CROWNS SSC-LRD6-CE PEDO CROWNS SSC-LRD7-CE
Upper E-Type		Lower E-Type	
Left	PEDO CROWNS SSC-ULE2-CE PEDO CROWNS SSC-ULE3-CE PEDO CROWNS SSC-ULE4-CE PEDO CROWNS SSC-ULE5-CE PEDO CROWNS SSC-ULE6-CE PEDO CROWNS SSC-ULE7-CE	Left	PEDO CROWNS SSC-LLE2-CE PEDO CROWNS SSC-LLE3-CE PEDO CROWNS SSC-LLE4-CE PEDO CROWNS SSC-LLE5-CE PEDO CROWNS SSC-LLE6-CE PEDO CROWNS SSC-LLE7-CE
Right	PEDO CROWNS SSC-URE2-CE PEDO CROWNS SSC-URE3-CE PEDO CROWNS SSC-URE4-CE PEDO CROWNS SSC-URE5-CE PEDO CROWNS SSC-URE6-CE PEDO CROWNS SSC-URE7-CE	Right	PEDO CROWNS SSC-LRE2-CE PEDO CROWNS SSC-LRE3-CE PEDO CROWNS SSC-LRE4-CE PEDO CROWNS SSC-LRE5-CE PEDO CROWNS SSC-LRE6-CE PEDO CROWNS SSC-LRE7-CE
PEDO CROWNS SSC-KIT-CE (48 CROWNS) PEDO CROWNS SSC-TRAY-CE			

Model : KIDS RING CROWNS series

Upper D-Type		Lower D-Type	
Left	KIDS RING CROWN D-UL-2 KIDS RING CROWN D-UL-3 KIDS RING CROWN D-UL-4 KIDS RING CROWN D-UL-5 KIDS RING CROWN D-UL-6 KIDS RING CROWN D-UL-7	Left	KIDS RING CROWN D-LL-2 KIDS RING CROWN D-LL-3 KIDS RING CROWN D-LL-4 KIDS RING CROWN D-LL-5 KIDS RING CROWN D-LL-6 KIDS RING CROWN D-LL-7
Right	KIDS RING CROWN D-UR-2 KIDS RING CROWN D-UR-3 KIDS RING CROWN D-UR-4 KIDS RING CROWN D-UR-5 KIDS RING CROWN D-UR-6 KIDS RING CROWN D-UR-7	Right	KIDS RING CROWN D-LR-2 KIDS RING CROWN D-LR-3 KIDS RING CROWN D-LR-4 KIDS RING CROWN D-LR-5 KIDS RING CROWN D-LR-6 KIDS RING CROWN D-LR-7
Upper E-Type		Lower E-Type	
Left	KIDS RING CROWN E-UL-2 KIDS RING CROWN E-UL-3 KIDS RING CROWN E-UL-4 KIDS RING CROWN E-UL-5 KIDS RING CROWN E-UL-6 KIDS RING CROWN E-UL-7	Left	KIDS RING CROWN E-LL-2 KIDS RING CROWN E-LL-3 KIDS RING CROWN E-LL-4 KIDS RING CROWN E-LL-5 KIDS RING CROWN E-LL-6 KIDS RING CROWN E-LL-7
Right	KIDS RING CROWN E-UR-2 KIDS RING CROWN E-UR-3 KIDS RING CROWN E-UR-4 KIDS RING CROWN E-UR-5 KIDS RING CROWN E-UR-6 KIDS RING CROWN E-UR-7	Right	KIDS RING CROWN E-LR-2 KIDS RING CROWN E-LR-3 KIDS RING CROWN E-LR-4 KIDS RING CROWN E-LR-5 KIDS RING CROWN E-LR-6 KIDS RING CROWN E-LR-7
KIDS RING CROWN KIT (48 CROWNS)			

Classification : Class IIa by Rule 8 of AnnexⅨ, MDD 93/42/EEC as amended by Directive 2007/47/EC

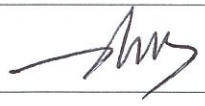
Conformity Assessment Route : AnnexⅡ(excluding section4), MDD 93/42/EEC as amended by Directive 2007/47/EC

Relevant Standards: EN 1041:2008, EN 1641:2009, ISO 15223-1:2016, ISO 13485:2016, ISO 10993-1:2018, ISO 14971:2019, ISO 14155:2020, ISO 7000:2019, ISO 10271:2020, EN ISO 22674:2016

We herewith declare that the above mentioned products meet the provisions of the Council Directive **93/42/EEC as amended by Directive 2007/47/EC** for medical devices. All supporting documentation is retained under the premises of the manufacturer.

KIDS CROWN, PEDO CROWNS, KIDS RING CROWN are subject to procedure set out in **AnnexⅡ(excluding section4)** of **MDD 93/42/EEC as amended by Directive 2007/47/EC** under the supervision of Notified body Number 1639,
SGS BELGIUM NV, SGS House, Noorderlaan 87 – 2030 Antwerpen, Belgium.

Place, Date of issue : Seoul, Korea 08 March , 2022

	Department/Title	Name	Signature
Approval	Quality Team Leader	MIN-SOO KIM	

Director on behalf of Shinhung Co., Ltd.