SHINHUNG

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

EC Declaration of Conformity

Manufacturer : Shinhung Co., Ltd.

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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 : Artificial teeth, crown and temporary

Model : PERMA CROWN (Export Name for U.S.A. : PERMANENT CROWNS)

Upper Type		Lower Type	
Left	PERMA CROWN 6-UL-2, PERMA CROWN 6-UL-3 PERMA CROWN 6-UL-4, PERMA CROWN 6-UL-5 PERMA CROWN 6-UL-6, PERMA CROWN 6-UL-7	Left	PERMA CROWN 6-LL-2, PERMA CROWN 6-LL-3 PERMA CROWN 6-LL-4, PERMA CROWN 6-LL-5 PERMA CROWN 6-LL-6, PERMA CROWN 6-LL-7
Right	PERMA CROWN 6-UR-2, PERMA CROWN 6-UR-3 PERMA CROWN 6-UR-4, PERMA CROWN 6-UR-5 PERMA CROWN 6-UR-6, PERMA CROWN 6-UR-7	Right	PERMA CROWN 6-LR-2, PERMA CROWN 6-LR-3 PERMA CROWN 6-LR-4, PERMA CROWN 6-LR-5 PERMA CROWN 6-LR-6, PERMA CROWN 6-LR-7
PERMA CROWN KIT (24CROWNS) PERMA CROWN KIT (48CROWNS) PERMA CROWN KIT (96CROWNS)			

Model : PERMANENT CROWNS

Upper Type		Lower Type	
Left	PERMANENT CROWNS SSC-6UL2-CE PERMANENT CROWNS SSC-6UL3-CE PERMANENT CROWNS SSC-6UL4-CE PERMANENT CROWNS SSC-6UL5-CE PERMANENT CROWNS SSC-6UL6-CE PERMANENT CROWNS SSC-6UL7-CE	Left	PERMANENT CROWNS SSC-6LL2-CE PERMANENT CROWNS SSC-6LL3-CE PERMANENT CROWNS SSC-6LL4-CE PERMANENT CROWNS SSC-6LL5-CE PERMANENT CROWNS SSC-6LL6-CE PERMANENT CROWNS SSC-6LL7-CE
Right	PERMANENT CROWNS SSC-6UR2-CE PERMANENT CROWNS SSC-6UR3-CE PERMANENT CROWNS SSC-6UR4-CE PERMANENT CROWNS SSC-6UR5-CE PERMANENT CROWNS SSC-6UR6-CE PERMANENT CROWNS SSC-6UR7-CE	Right	PERMANENT CROWNS SSC-6LR2-CE PERMANENT CROWNS SSC-6LR3-CE PERMANENT CROWNS SSC-6LR4-CE PERMANENT CROWNS SSC-6LR5-CE PERMANENT CROWNS SSC-6LR6-CE PERMANENT CROWNS SSC-6LR7-CE
PERMANENT CROWNS SSC-PKIT-CE (24CROWNS) PERMANENT CROWNS SSC-PKITM-CE (96CROWNS) PERMANENT CROWNS SSC-PTRAY-CE			

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 here with 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.

PERMA CROWN, PERMANENT CROWNS are subject to procedure set out in **AnnexⅡ(excludingsection4)** of **MDD 93/42/EEC as amended by Directive 2007/47/EC** under the supervision of Notified body 1639, **SGS BELGIUM NV,** SGS House, Noorderlaan 87 – 2030 Antwerpen, Belgium.

Place, Date of issue : Seoul, Korea 05 January , 2022

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

Director on behalf of Shinhung Co., Ltd.