

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-1220502

Manufacturer: HASS CORP.
77-14, Gwahakdanji-ro, Gangneung-si, Gangwon-do, Republic of KOREA

Product(s): Ceramic Blocks and Crowns for Dental
1. Ceramic Block
2. Glass Ceramic Block
3. Glass Ceramic Block & Ingot
4. Ceramic Pediatric Preformed Crown
5. Lithium Disilicate Glass Ceramic Block & Ingot
6. Lithium Disilicate Glass Ceramic Block
7. Hybrid Ceramic Block

Model(s):
1. Zirtooth, Zirtooth Multi NEO, Zirtooth Multiluster, Zirtooth Ultraluster
2. Rosetta BM
3. Rosetta SM, Rosetta SP
4. ZIRKIZ
5. Amber Mill, Amber Mill Meso, Amber Press, Amber LiSi-POZ, Amber Press Master, Amber LiSi-POM
6. Amber Mill Direct, Amber Mill Q
7. Amber Mill H

Reference Report No: MM0232-P006-R01, MM0232-P006-R02, MM0232-P007-R01, MM0232-P008-R01, MM0232-P008-R02, MM0232-P009-R01, MM0232-P009-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

This EC certificate is valid till 2024-05-26.

Issue Date: 2012-07-23
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Deputy General Manager