SZUTEST

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-2113901

Manufacturer: **Izenimplant Co., Ltd.**
1, 2Dong, 26-32, Suworam 4-gil, Seotan-myeon, Pyeongtaek-si, Gyeonggi-do, Republic of KOREA

Product(s):
1. Sterile Dental Implant
2. Non-Sterile Dental Abutments
3. Sterile Dental Abutment
4. Sterile Orthodontic Screw
5. Dental Surgical Instruments
6. Orthodontic Surgical Instruments

Model(s):
1. ZENEX MULTI Fixture, ZENEX PLUS Fixture
2. Cemented Abutment, Angled Abutment, Ball Abutment, Multi Straight Abutment, Multi Angled Abutment, Multi Ti Link Cylinder, Ti Link Abutment, FreeMilling Abutment, Ti Blank Abutment, Temporary Abutment, Multi Temporary Cylinder, CCM Cast Abutment, Multi CCM Cast Cylinder
3. Healing Abutment, Cover Screw, Multi Healing Cap
4. Multi Anchor
5. ZENEX SURGERY KIT, ZENEX EASY SURGERY KIT, ZENEX SUPERWIDE KIT, ZENEX PROSTHETIC KIT
6. Drill for Orthodontic, Driver Shaft for Contra Angle

Reference Report No: MM0864-P001-R01, MM0864-P001-R02, MM0864-P001-R03, MM0864-P001-R04, MM0864-P001-R05

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), 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 II, Section 5 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: 2021-05-19

Rukiye BALKAN
Deputy General Manager

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