



CERTIFICATE



## EC Certificate

### Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-12-169

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

#### Organization:

### AGS MEDİKAL ÜRÜNLERİ İTHALAT İHRACAT TİCARET ANONİM ŞİRKETİ

HQ: KATİP SALİH SOK. NO: 111 KOŞUYOLU, KADIKÖY, İSTANBUL, TURKEY  
FACTORY: SEYİT AHMET MAHALLESİ 1 NOLU CAD. AGS MEDİKAL APT. NO:8  
BEŞİKDÜZÜ, TRABZON, TURKEY

#### Products: Dental Implant System and Dental Drill

The products defined at the enclosure which is the part of this certificate and contains 4 (Four) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.3773.09  
**Date of first issue:** 08 June 2012  
**Date of last issue:** 24 July 2020  
**Revision Number:** 13  
**Expiry Date:** 27 May 2024

Muhteşem Gökhan Yücel  
Head of Notified Body

24 July 2020, Istanbul, Turkey



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Enclosure of the EC Certificate:

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Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II.3

Certificate Number: 1984-MDD-12-169, Revision Number: 13

Concerned medical devices;

Product Description	Product Name
Bone Level Implants, Abutments, Screws, Solid Caps	Bone Level Mini Fixture Straight RBM, Bone Level Fixture Hybrid RBM, Bone Level Wide Fixture Hybrid RBM, Bone Level Fixture Aggressor RBM Bone Level Mini Couple Abutment, Bone Level Couple Abutment, Bone Level Mini Couple Abutment Non-Hex, Bone Level Couple Abutment Non-Hex, Bone Level Mini Angled Abutment, Bone Level Angled Abutment, Bone Level Mini Angled Abutment Non-Hex, Bone Level Angled Abutment Non-Hex, Bone Level Mini Multi Abutment, Bone Level Multi Abutment, Bone Level Mini Multi Abutment Non-Hex, Bone Level Multi Abutment Non-Hex, Bone Level Mini Octa Abutment, Bone Level Octa Abutment, Bone Level Mini O-Ring Abutment, Bone Level O-Ring Abutment, Bone Level Mini Solid Abutment, Bone Level Solid Abutment, Bone Level Mini Healing Abutment, Bone Level Healing Abutment, Bone Level Temporary Abutment, Bone Level Temporary Abutment Non-Hex, Bone Level Mini Locator Abutment, Bone Level Locator Abutment,

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Concerned medical devices;

Product Description	Product Name
Bone Level Implants, Abutments, Screws, Solid Caps	Bone Level Mini Short Sinus Abutment, Bone Level Mini Ti-Base Abutment, Bone Level Ti-Base Abutment, Bone Level Mini Premill Abutment, Bone Level Premill Abutment, Bone Level Mini Sinus Abutment Screw, Bone Level Implant Mini Closing Screw, Bone Level Implant Closing Screw, Bone Level Mini Abutment Screw, Bone Level Abutment Screw, Bone Level Mini Solid Abutment Healing Cap, Bone Level Solid Abutment Healing Cap
Tissue Level Implants, Abutments, Screws, Solid Caps	Tissue Level Fixture Hybrid RBM, Tissue Level Wide Fixture Hybrid RBM, Tissue Level Fixture Straight RBM, Tissue Level Couple Abutment, Tissue Level Couple Abutment Wide, Tissue Level Couple Abutment Non-Octa, Tissue Level Couple Abutment Wide Non-Octa, Tissue Level Angled Abutment, Tissue Level Multi Abutment, Tissue Level Multi Abutment Non-Octa, Tissue Level Octa Abutment, Tissue Level Synocta Abutment, Tissue Level Synocta Abutment Non-Octa, Tissue Level O-Ring Abutment, Tissue Level Solid Abutment, Tissue Level Solid Abutment Large, Tissue Level Healing Abutment, Tissue Level Healing Abutment Wide, Tissue Level Temporary Abutment,

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Concerned medical devices;

Product Description	Product Name
Tissue Level Implants, Abutments, Screws, Solid Caps	Tissue Level Temporary Abutment Non-Octa, Tissue Level Locator Abutment, Tissue Level Premill Abutment, Tissue Level Wide Premill Abutment, Tissue Level Implant Closing-Screw Large, Tissue Level Implant Closing-Screw Small, Tissue Level Closing Screw Wide, Tissue Level Abutment Screw, Tissue Level Solid Abutment Cap, Tissue Level Solid Abutment Large Cap
Common Components for Bone Level and Tissue Level Implants	Octa Abutment Screw, Octa Abutment Healing Cap, O-RING-R, O-RING-B, O-Ring Retainer, O-Ring Retainer/open, O-Ring Retainer/closed, Matrix Housing, Retention Insert
Solid Implants	Solid Fixture Mini Rough, Solid Fixture Regular Rough, Solid Fixture Regular Rough-Large Abutment, Solid Fixture Mini Smooth, Solid Fixture Regular Smooth, Solid Fixture Wide Smooth-Large Abutment

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Concerned medical devices;

Product Description	Product Name
Zygoma Implants, Abutments	Zygoma Implant, Oncological Zygoma Implant, Atrophic Maxillary Zygoma Implant, Zygoma Couple Abutment, Zygoma Healing Abutment, Zygoma Abutment Screw, Zygoma Healing Abutment Screw
Dental Drills	Straight Drill, Tapered Drill, Round Drill, Point Drill, Pilot Drill, Neck Drill, Taping Drill, Lindeman Drill, Lance Drill, Twist Drill, Bone Taping Drill, Bone Level Aggressive Reamer Drill, Tapered Aggressive Drill

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel  
Head of Notified Body

24 July 2020, Istanbul, Turkey