CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-19-608

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:

DTİ İMPLANT SİSTEMLERİ SANAYİ TİCARET ANONİM ŞİRKETİ

Head Office: Merkez Mah. Çavuşbaşı Cad. Aytekin Sokak No:5 D: 1-2 Çekmeköy, İstanbul, Turkey

Factory: Tübitak Gebze Yerleşkesi Teknoloji Serbest Bölgesi Yeni Teknoloji Binaları Eski Yemekhane Binası Gebze, Kocaeli, Turkey

Products: Dental Implant System and Dental Drill

The products defined at the enclosure which is the part of this certificate and contains two (2) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.5555.02
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Revision Number:	02
Expiry Date:	27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

24 May 2021, Istanbul, Turkey

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CERTIFICATE

Enclosure of the EC Certificate:

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-19-608, Revision Number: 02

Concerned medical devices;

Product	Types
Implant	DTI SLA Implant Ultra Mini, DTI SLA Implant Mini, DTI SLA Implant Standard, DTIACT Implant Ultra Mini, DTIACT Implant Mini, DTIACT Implant Standard, DTI AGGRESSIVE SLA Ultra Mini, DTI AGGRESSIVE SLA Mini, DTI AGGRESSIVE SLA Short-Mini, DTI AGGRESSIVE ACT Ultra Mini, DTI AGGRESSIVE ACT Mini, DTI AGGRESSIVE ACT Short-Mini, DTI SLA UNIFORM Implant Ultra Mini, DTI SLA UNIFORM Implant Mini, DTI ACT UNIFORM Implant Ultra Mini, DTI ACT UNIFORM Implant Mini, DTI MONO Implant, DTI MONO-BALL Implant, DTI MONO-FLEX Implant
Abutment	Abutment Straight Ultra Mini, Abutment Straight Mini, Abutment Straight Standard, Abutment Angled Ultra Mini, Abutment Angled Mini, Abutment Angled Standard, Ball Attachment Ultra Mini, Ball Attachment Mini, Ball Attachment Standard, Ball Attachment Cap Normal, Ball Attachment Cap Hard, Locator Cap,Ucla Abutment Standard, Ucla Abutment Mini, Telescopic Abutment Ultra Mini, Telescopic Abutment Mini, Telescopic Abutment Standard, Multi Unit Abutment Mini Straight, Multi Unit Abutment Mini Angled, Multi Unit Abutment Standard Straight, Multi Unit Abutment Standard Angled, Multi Unit Titanium Abutment, Multi Unit Ti-Base, Locator Abutment Ultra Mini, Locator Abutment Mini, Locator Abutment Standard, Ti Base Castable Abutment Manual, Ti-Base Abutment Ultra Mini, Ti-Base Abutment Mini, Ti-Base Abutment Standard, Ti-Base Angled Abutment Mini, Ti-Base Angled Abutment Standard, Peek Abutment Ultra Mini, Peek Abutment Mini, Peek Abutment Standard, Universal Abutment Ultra Mini, Universal Abutment Mini, Universal Abutment Standard, Premill Abutment Ultra Mini, Premill Abutment Mini, Premill Abutment Standard, Anatomical Straight Abutment Ultra Mini, Anatomical Straight Abutment Mini, Anatomical Straight Abutment Standard, Anatomical Angled Abutment Ultra Mini, Anatomical Angled Abutment Mini, Anatomical Angled Abutment Standard, Healing Abutment Ultra Mini, Healing Abutment Mini, Healing Abutment Standard, Healing Abutment - Ultra Mini Sinus, Healing Abutment - Mini Sinus, Healing Abutment - Standard Sinus, Multi Unit Healing Abutment

Muhteşem Gökhan Yücel
Head of Notified Body

24 May 2021, Istanbul, Turkey

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CERTIFICATE

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Certificate Number: 1984-MDD-19-608, Revision Number: 02

Concerned medical devices;

Product	Types
Dental Drill	Lance Drill, Ø2.3 – 7 Dental Drill, Ø2.3 – 8,5 Dental Drill, Ø2.3 – 10 Dental Drill, Ø2.3 – 11,5 Dental Drill, Ø2.3 – 13 Dental Drill, Ø2.3 – 15 Dental Drill, Ø3.0 – 10 Dental Drill, Ø3.0 – 11,5 Dental Drill, Ø3.0 - 13 Dental Drill, Ø3.0 – 15 Dental Drill, Ø3.5 – 7 Dental Drill, Ø3.5 – 8,5 Dental Drill, Ø3.5 – 10 Dental Drill, Ø3.5 – 11.5 Dental Drill, Ø3.5 – 13 Dental Drill, Ø3.5 – 15 Dental Drill, Ø4 – 7 Dental Drill, Ø4 – 8,5 Dental Drill, Ø4 – 10 Dental Drill, Ø4 – 11,5 Dental Drill, Ø4 – 13 Dental Drill, Ø4 – 15 Dental Drill, Ø4,5 – 7 Dental Drill, Ø4,5 – 8,5 Dental Drill, Ø4,5 – 10 Dental Drill, Ø4,5 – 11,5 Dental Drill, Ø4,5 – 13 Dental Drill, Ø4,5 – 15 Dental Drill, Ø5 – 7 Dental Drill, Ø5 – 8,5 Dental Drill, Ø5 – 10 Dental Drill, Ø5 – 11,5 Dental Drill, Ø5 – 13 Dental Drill, Ø5 – 15 Dental Drill, Hard-Taper Dental Drill Cortical Ø3.5, Hard-Taper Dental Drill Cortical Ø4.0, Hard-Taper Dental Drill Cortical Ø4.5, Hard-Taper Dental Drill Cortical Ø5.0, Ø2,3 AG Dental Drill, Ø2,8 AG Dental Drill, Ø3,0 AG Dental Drill, Ø3,5 AG Dental Drill, Ø4,0 AG Dental Drill, Ø4,5 AG Dental Drill, Ø5,0 AG Dental Drill, Ø5,5 AG Dental Drill, Ø6,0 AG Dental Drill, Ø3,0 AG Cortical Dental Drill, Ø3,5 AG Cortical Dental Drill, Ø4,0 AG Cortical Dental Drill, Ø4,5 AG Cortical Dental Drill, Ø5,0 AG Cortical Dental Drill, Ø5,5 AG Cortical Dental Drill, Ø6,0 AG Cortical Dental Drill, Ø3,0 AG Bone Expander Drill, Ø3,5 AG Bone Expander Drill, Ø4,0 AG Bone Expander Drill, Ø4,5 AG Bone Expander Drill, Ø5,0 AG Bone Expander Drill, Ø5,5 AG Bone Expander Drill, Ø6,0 AG Bone Expander Drill

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

24 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

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