NTA® IMPLANT

Sertifika

NTA
IMPLANT
CONFIDENCE
IN STABILITY!

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

(EU) 2017/745 Medical Device Regulation Annex IX

Chapter I and III

Certificate Number: MDR.2292-2025/0029

Manufacturer Name	: Pilatus Swiss Dental Gmbh
Manufacturer Address	: Dorfchärn CH - 6243 Egolzwil SWITZERLAND
Single Registration Number-SRN	: CH-MF-000025604
Authorized Representative Name (If any)	: NTA İmplant Grup Sanayi Ticaret A.Ş.
Authorized Representative Address	: Mehmetçik Mah. 1241 Sk. No:4 Muratpaşa ANTALYA / TÜRKİYE
Device/Device Group Name **Detailed information is in the attached device list.*	: Sterile Dental Implant Non-Sterile Dental Abutment&Accessories

Based on the conformity assessment of the quality management system of the above-mentioned manufacturer according to Annex IX Chapter I and Chapter III of (EU) 2017/745 Medical Device Regulation, UDEM A.Ş. declares that the relevant requirements are met for the products listed in this certificate

The manufacturer has established, documented and implemented a quality management system that is subject to periodic surveillance assessments by UDEM A.Ş. in accordance with Annex IX Chapter I Section 3 of the related regulation.

All relevant reports starting with the number UDEM.0599 of the customer organization referred to below summarize the outcome of the assessments/reviews and refer to the relevant common specifications, if any, harmonized standards and test reports. Upon request, these reports are available in UDEM A.Ş. records in accordance with Section 10 of Chapter II of Annex XII of the MDR. For Class III and certain Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of (EU) 2017/745 Medical Device Regulation covered by this certification, an EU Technical Documentation Assessment Certificate is required before they can be placed on the market.

Customer Number	: UDEM.0599
Issue Date	: 14.11.2025
Revision Date/No	: - / -
Validity Date	: 17.12.2028
Previous Certificate(s) No., if any	: Not Applicable.

General Manager
Stamp - Signature

UDEM APPROVED 2292

UDEM A.Ş. is a Notified Body under the (EU) 2017/745 Medical Device Regulation. Notified Body No: 2292

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EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

(EU) 2017/745 Medical Device Regulation Annex IX

Chapter I and III

Certificate Number: MDR.2292-2025/0029

ANNEX: DEVICE LIST WITHIN THE SCOPE OF THE CERTIFICATE

DEVICE PRODUCT/DEVICE GROUP	RISK CLASS	EMDN CODE	INTENDED USE *Should be specified only for class IIb and class III devices.*
Sterile Dental Implant			
NTA Implant	IIb	P01020101	Intended to replace one or more missing teeth in the upper or lower jaw in partially or fully edentulous patients in order to restore shewing function.
NTA Implant-Tissue Level			
NTA Implant Spure			
NTA Hybrid Implant			
Non-Sterile Dental Abutment			
NTA Implant - NTA Abutment & Accessories	IIb	P01020180	Abutment is a medical device that provides the connection between the prosthesis and the implant to enable the appropriate prosthesis that is used after the implant placement in the treatment of dental deficiency by dentist.
NTA Implant - NTA Tissue Level Abutment & Accessories			
NTA Implant - NTA Abutment Spure & Accessories			
NTA Shorter Implant - NTA Shorter Abutment & Accessories			
NTA Hybrid Implant - NTA Hybrid Abutment & Accessories			

**Limitations on the conditions of the certificate: Not Applicable.*

CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Revision Explained**
00	14.11.2025	Reissue of the certificate within the scope of MDR Certificate (Certificate No: M.2024.MDR.1059 / Date of Issue: 18.12.2024) transfer

UDEM APPROVED 2292

UDEM A.Ş. is a Notified Body under the (EU) 2017/745 Medical Device Regulation. Notified Body No: 2292

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KIOSCERT®
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This Certificate

PILATUS SWISS DENTAL GMBH

Of the Company

DORFCHÄRN 6243 EGOLZWIL SWITZERLAND

The facilities at the addresses have been audited by KIOSCERT and Quality Management System

ISO 9001:2015

It has been observed that the conditions are applied with in the following scope

Certification Scope

DESIGN, DEVELOPMENT, PRODUCTION, DISTRIBUTION AND SALE OF DENTAL IMPLANT SYSTEM (ENDOSSEOUS DENTAL IMPLANT, ENDOSSEOUS DENTAL IMPLANT ABUTMENT, ENDOSSEOUS DENTAL IMPLANT ACCESSORIES, SURGICAL KIT, SURGICAL INSTRUMENT, ENDOSSEOUS DENTAL IMPLANT LAB COMPONENTS), PRODUCTION, DISTRIBUTION AND SALE OF DIGITAL INTRA ORAL SCANNER SYSTEMS

Technical Area: EA Code: 19, 23

Certificate Number: QMS-26-0904-PIL

Certificate First Issue Date: 09.04.2026

Certificate Release Date: 09.04.2026

Certificate Validity Date: 08.04.2027

Certificate Revision Number and Date : / 00 / --

This certificate is valid for a period of three (3) years from the date of initial issuance, provided that compliance with KIOSCERT certification rules is maintained and the annual surveillance audits are successfully completed. The validity of this certificate is subject to the satisfactory completion of annual surveillance audits.

FR.14.09 / 01.03.2021 / 06 / 06.01.2026

NAC
MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-004-MS

KIOSCERT®
CERTIFICATE
ISO 9001
Quality Management System

KIOSCERT CERTIFICATION SERVICES LIMITED
KIOSCERT CERTIFICATE
Approval

KIOSCERT CERTIFICATION SERVICES LIMITED
24 Brookdale London England N11 1BL
Phone: +44 20 8058 0195
Web: www.kioscert.co.uk E mail: info@kioscert.co.uk | info@kioscert.com
Company Registered in England and Wales with Company Number 14284313

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This Certificate

PILATUS SWISS DENTAL GMBH

Of the Company

DORFCHÄRN 6243 EGOLZWIL SWITZERLAND

The facilities at the addresses have been audited by KIOSCERT and Customer Satisfaction Management System

ISO 10002:2018

It has been observed that the conditions are applied with in the following scope

Certification Scope

DESIGN, DEVELOPMENT, PRODUCTION, DISTRIBUTION AND SALE OF DENTAL IMPLANT SYSTEM (ENDOSSEOUS DENTAL IMPLANT, ENDOSSEOUS DENTAL IMPLANT ABUTMENT, ENDOSSEOUS DENTAL IMPLANT ACCESSORIES, SURGICAL KIT, SURGICAL INSTRUMENT, ENDOSSEOUS DENTAL IMPLANT LAB COMPONENTS), PRODUCTION, DISTRIBUTION AND SALE OF DIGITAL INTRA ORAL SCANNER SYSTEMS

Technical Area: EA Code: 19, 23

Certificate Number: CSMS-26-0904-PIL

Certificate First Issue Date: 09.04.2026

Certificate Release Date: 09.04.2026

Certificate Validity Date: 08.04.2027

Certificate Revision Number and Date : / 00 / --

FR.14.09 / 01.03.2021 / 06 / 06.01.2026

This certificate is valid for a period of three (3) years from the date of initial issuance, provided that compliance with KIOSCERT certification rules is maintained and the annual surveillance audits are successfully completed. The validity of this certificate is subject to the satisfactory completion of annual surveillance audits.

KIOSCERT CERTIFICATE ISO 10002 Customer Satisfaction Management System

KIOSCERT CERTIFICATION SERVICES LIMITED

Approval

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Company Registered in England and Wales with Company Number 14284313

KIOSCERT

INTERNATIONAL FIRST CERTIFICATION

IFC GLOBAL

CERTIFICATE

Pilatus Swiss Dental GMBH

Dorfchärn 6243 Egolzwil Switzerland

IFC Global Certification confirms that the above-named organization's management system has been assessed and complies with the requirements of the following standard.

Standard:

ISO 13485:2016

Scope:

Design, development, production, distribution and sale of dental implant system (endosseous dental implant, endosseous dental implant abutment, endosseous dental implant accessories, surgical kit, surgical instrument, endosseous dental implant lab components), production, distribution and sale of dijital intra oral scanner systems

Initial Date	: 25.09.2025
Issue Date	: 25.09.2025
Revision Date	: 0
Date of Validity	: 24.09.2026
Expiry Date	: 24.09.2028
Certificate No	: IFC-E-9-25-1381

CB-MS-8147

Approval

Head Office: IFC GLOBAL LLC | **Key Location: IFC GLOBAL SERTİFİKASYON MUAYENE VE EĞİTİM HİZMETLERİ ANONİM ŞİRKETİ**
3001 Sw 3rd Ave Miami, FL. US 33129 | Adalet Mah. 2132/2 Sokak No:3 Trend Office D:45 Bayraklı İzmir Türkiye
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www.ifcglobal.us | www.ifcglobal.com.tr

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This Certificate

PILATUS SWISS DENTAL GMBH

Of the Company

DORFCHÄRN 6243 EGOLZWIL SWITZERLAND

The facilities at the addresses have been audited by KIOSCERT and Good Manufacturing Practices

GMP

It has been observed that the conditions are applied with in the following scope

Certification Scope

DESIGN, DEVELOPMENT, PRODUCTION, DISTRIBUTION OF DENTAL IMPLANT SYSTEM (ENDOSSEOUS DENTAL IMPLANT, ENDOSSEOUS DENTAL IMPLANT ABUTMENT, ENDOSSEOUS DENTAL IMPLANT ACCESSORIES, SURGICAL INSTRUMENT), PRODUCTION OF MASK

Certificate Number: GMP-26-0904-PIL

Certificate First Issue Date: 09.04.2026

Certificate Release Date: 09.04.2026

Certificate Validity Date: 08.04.2027

Certificate Revision Number and Date : / 00 / --

FR.14.09 / 01.03.2021 / 06 / 06.01.2026

This certificate is valid for a period of three (3) years from the date of initial issuance, provided that compliance with KIOSCERT certification rules is maintained and the annual surveillance audits are successfully completed. The validity of this certificate is subject to the satisfactory completion of annual surveillance audits.

KIOSCERT CERTIFICATE ISO 22716-GMP

KIOSCERT CERTIFICATION SERVICES LIMITED

Approval

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Company Registered in England and Wales with Company Number 14284313

KIOSCERT

CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-20-638

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:

NTA İMPLANT TİCARET VE SANAYİ LİMİTED ŞİRKETİ

TAHILPAZARI MAH. İSMET PAŞA CAD. ZEYNEP ERTUĞRUL APT. NO:43/3
MURATPAŞA / ANTALYA, TURKEY

Product: Dental Implant System

The products defined at the enclosure which is the part of this certificate and contains one (1) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.5850.01
Date of first issue:	07 February 2020
Date of last issue:	24 September 2020
Revision Number:	01
Expiry Date:	27 May 2024

24 September 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
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T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

TÜRKİYE CUMHURİYETİ'NİN YÜZÜNCÜ YILI

Sayı : E-61749811-511.99-1534575 11.07.2024
Konu : 2023/KK-1 Sayılı Duyuru Başvuruları Hk.

NTA İMPLANT TİCARET VE SANAYİ LTD. ŞTİ.
Tahılpazarı Mah. İsmetpaşa Cad. Zeynep Ertuğrul Apt. No:43/3 MURATPAŞA ANTALYA

İlgi : 10.07.2024 tarihli, E-48535386-511.01.99-3274965 sayılı, 6166562 işlem takipli yazınız

İlgi yazıda yer alan ve 1984-MDD-20-638 numaralı EC sertifikanın belge geçerlilik süresinin uzatılması talebinizle ilgili olan başvurunuz incelenmiştir.

Avrupa Komisyonu'nun tıbbi cihazların tedarik edilememe riskini azaltmak amacıyla "*(AB) 2017/745 sayılı ve (AB) 2017/746 sayılı Tüzükleri belirli tıbbi cihazların ve in vitro tanı amaçlı tıbbi cihazların geçiş hükümlerini tadil eden (AB) 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü*" 20 Mart 2023 tarihinden itibaren yürürlüğe girecek şekilde 20 Mart 2023 tarihinde AB Resmi Gazetesinde yayımlanmıştır.

AB'nin güncel tıbbi cihaz mevzuatına uyum çalışmaları kapsamında;*(AB) 2023/607 Sayılı Avrupa Parlamentosu ve Konsey Tüzüğü'ne* paralel olarak, "*Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik*" ve "*İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde Değişiklik Yapılmasına Dair Yönetmelik*" adlı Yönetmeliklerimiz 2/4/2023 tarihli Resmi Gazete 'de yayımlanmış olup, *Tıbbi Cihaz Yönetmeliği* ve *İn Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde* söz konusu değişikler yapılmıştır.

Bu kapsamda, söz konusu geçiş hükümlerinin uygulanmasına yönelik başvuruların usul ve esaslarının açıklandığı "*2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru*" adlı Duyurumuz 3/4/2023 tarihinde Kurumumuz web sitesinde ve ÜTS Portal'da yayımlanarak yürürlüğe girmiştir.

Bu minvalde ilgili başvuru "*2023/KK-1 Sayılı (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru*" kapsamında değerlendirilmiş olup, başvurudaki 1984-MDD-20-638 numaralı EC sertifikanın geçerlilik süresinin **31.12.2027** tarihine kadar uzatılması uygun görülmüştür. Bu bağlamda, "***2023/KK-2 Sayılı*** (AB) 2023/607 Sayılı Tüzük Hükümlerinin Uygulanmasına Dair Duyuru" adlı Duyurumuz kapsamında ÜTS'de belge kayıt/güncelleme başvurusu yapılması ve ilgili başvuruya bu cevabi yazımız ve eklerinin de eklenmesi hususunda;

Bilgilerinizi ve gereğini rica ederim.

Dr. Mehmet Hakan FIRAT
Kurum Başkanı a.
Kurum Başkan Yardımcısı

Ek-1: Üretici Beyanı
Ek-2: Teyit Mektubu

Söğütözü Mahallesi, 2176.Sokak No:5 06520 Çankaya/ANKARA
Telefon No: (0 312) 218 30 00 Faks No: (0 312) 218 34 60
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Kep Adresi: titck@hs01.kep.tr

KING CERT

CERTIFICATE

NTA İmplant Grup Sanayi Ticaret A.Ş.

Mehmetçik Mah. 1241 Sk. No: 4 Muratpaşa Antalya Türkiye

The above-mentioned organization implements and maintains a management system in the following scope, and its compliance with the standard has been approved by KingCert.

ISO 9001:2015

Quality Management System

Scope : Design, Development, Production and Sales of Intrabony Dental Implants and Abutments

IAF/EA Code: 23

IAS ACCREDITED Management Systems Certification Body MSCB-196

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

This certificate is valid during above mentioned company perform the requirements of ISO 9001:2015 standard and fulfill all responsibilities to KingCert.

Certificate Publication Date : 13.02.2026
Cert. Last Issue Date : 13.02.2026
Cert. Expiry Date : 12.02.2027
Certificate Number : I1770966215Q

King Cert International Certification Ltd.
CEO

King Cert International Certification Ltd.
Tsarigradsko Shose Blvd. No: 133
Bic Izot Floor 6., Office No: 603
1784 Sofia Bulgaria
info@KingCert.com
FR.25 / 01.09.2016 / 27.11.2024 / 06

Hereby, King Cert International Certification Ltd., certifies that the above stated company have the appropriate management system acording to the requirements of the above standards. This certificate is valid for three years as long as the system effectively maintained and surveillance audits are carried out. Certification Period Expiry Date is 12.02.2029 . The validity of the certificate can be checked through www.KingCert.com . The certificate is property of King Cert International Certification Ltd. and shall be returned if so requested.

WQR
WORLD QUALITY REGISTRAR

CERTIFICATE

NTA İmplant Grup Sanayi Ticaret A.Ş.

Mehmetçik Mah. 1241 Sk. No: 4 Muratpaşa Antalya Türkiye

This certificate is issued for the above-mentioned company, according to the following scope given by the WQR Certification.

ISO 10002:2018

Customer Satisfaction Management System

Scope of Certification

Design, Development, Production and Sales of Intrabony Dental Implants and Abutments

World Accreditation Services

ACCREDITED
CERTIFICATION BODIES
EN ISO/IEC 17021

Certificate No : W-260224-C
Publication Date : 13.02.2026
Last Issue Date : 13.02.2026
Expiry Date : 12.02.2027

WQR International Certification Ltd.
Director

The validity of the certificate can be checked through www.wqrcert.com or www.the-was.com.

WORLD QUALITY REGISTRAR

CERTIFICATE

NTA İmplant Grup Sanayi Ticaret A.Ş.

Mehmetçik Mah. 1241 Sk. No: 4 Muratpaşa Antalya Türkiye

This certificate is issued for the above-mentioned company, according to the following scope given by the WQR Certification.

ISO 13485:2016

Medical Devices Quality Management System

Scope of Certification

Design, Development, Production and Sales of Intrabony Dental Implants and Abutments. Production and Sales of Mask and Coverall.

World Accreditation Services

ACCREDITED
CERTIFICATION BODIES
EN ISO/IEC 17021

Certificate No : W-260223
Publication Date : 13.02.2026
Last Issue Date : 13.02.2026
Expiry Date : 12.02.2027

WQR International Certification Ltd.
Director

The validity of the certificate can be checked through www.wqrcert.com or www.the-was.com.