NTA® IMPLANT

Certificate

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IMPLANT
CONFIDENCE
IN STABILITY!

EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX
Chapter I and III (Class IIa, IIb and III Devices)
Certificate Number: M.2024.MDR.1059

Manufacturer Name	: Pilatus Swiss Dental Gmbh
Manufacturer Address	: Dorfchärn CH - 6243 Egolzwil / Switzerland
Single registration number-SRN	: CH-MF-000025604
Authorised Representative Name ***(If applicable)***	: NTA İmplant Grup Sanayi Ticaret A.Ş.
Authorised Representative Address	: Mehmetçik mah. 1241 sk. No: 4 Muratpaşa, Antalya, Türkiye,
Product Scope	: See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality management system in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III, UDEM Adriatic d.o.o. hereby declares that the requirements of Annex IX (Chapter I and Chapter III) of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.
The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according to Annex IX Chapter I Section 3 of the aforementioned Regulation.
The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.
For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Technical Documentation Assessment Certificate is required before placing them on the market.

Report Number	: MDR.1235
Date of Issue	: 18/12/2024
Recertification Date	: -
Reissue Date/No	: -
Date of Expiry	: 17/12/2028

If any, Previous Certificate(s) No: -

UDEM Adriatic d.o.o.
General Manager

UDEM Adriatic d.o.o. UDEM 2696

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

Address: Radnička cesta 54/ R3 Zagreb– Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

EU Technical Documentation Assessment Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX Chapter II
Certificate Number: M.2024.MDR.1059-1

Manufacturer Name	: Pilatus Swiss Dental Gmbh
Manufacturer Address	: Dorfchärn CH - 6243 Egolzwil / Switzerland
Single registration number-SRN	: CH-MF-000025604
Authorised Representative Name ***(If applicable)***	: NTA İmplant Grup Sanayi Ticaret A.Ş.
Authorised Representative Address	: Mehmetçik mah. 1241 sk. No: 4 Muratpaşa, Antalya, Türkiye,
Product Scope	: See the product list on the following page(s).

Based on the assessment of technical documentation for the abovementioned manufacturer in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter II, UDEM Adriatic d.o.o. hereby declares that the technical documentation of the listed products in this certificate meets the applicable requirements of the Regulation (EU) 2017/745.
The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards, and test reports.
For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Quality Management System Certificate in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III is also required before placing them on the market.
The validity of this certificate is dependent on the validity of the accompanying EU Quality Management System Certificate.

Report Number	: MDR.1235
Date of Issue	: 18/12/2024
Recertification Date	: -
Reissue Date/No	: -
Date of Expiry	: 17/12/2028

If any, Previous Certificate(s) No: -

UDEM Adriatic d.o.o.
General Manager

UDEM Adriatic d.o.o. UDEM 2696

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

Address: Radnička cesta 54/ R3 Zagreb– Croatia
E-Mail: info@udemadriatic.com **Web:** www.udemadriatic.com

KIOSCERT
CERTIFICATE

CERTIFICATE

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 within 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 First Issue Date / 24.03.2021

Certificate Validity Date / 23.03.2026

Certificate Release Date / 19.03.2025

Certificate No / QMS-21-2403-PIL

Certificate Revision Number and Date / 00 / --

Certificate Period / 3 Years

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

ISO 9001 KIOSCERT CERTIFICATE

KIOSCERT CERTIFICATION SERVICES LIMITED

Approval

KIOSCERT CERTIFICATION SERVICES LIMITED
24 Brookdale London England N11 1BL
Phone : +44 077 486 18146
Web : www.kioscert.co.uk E mail : info@kioscert.co.uk | support@kioscert.co.uk
Certificate validity information **www.kioscert.co.uk** you can check at.
Company Registered in England and Wales with Company Number 14284313

KIOSCERT

KIOSCERT
CERTIFICATE

CERTIFICATE

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 First Issue Date / 21.03.2022

Certificate Validity Date / 20.03.2026

Certificate Release Date / 19.03.2025

Certificate No / CSMS-22-2103-PIL

Certificate Revision Number and Date / 00 / --

Certificate Period / 3 Years

KIOSCERT CERTIFICATION SERVICES LIMITED

Approval

KIOSCERT CERTIFICATION SERVICES LIMITED
24 Brookdale London England N11 1BL
Phone : +44 077 486 18146
Web : www.kioscert.co.uk E mail : info@kioscert.co.uk | support@kioscert.co.uk
Certificate validity information **www.kioscert.co.uk** you can check at.
Company Registered in England and Wales with Company Number 14284313

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KIOSCERT
CERTIFICATE

CERTIFICATE

This certificate

PILATUS SWISS DENTAL GMBH

Of the Company

DORFCHÄRN 6243 EGOLZWIL SWITZERLAND

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

ISO 13485:2016

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

Certificate First Issue Date / 24.03.2021

Certificate Validity Date / 23.03.2026

Certificate Release Date / 19.03.2025

Certificate No / MDMS-21-2403-PIL

Certificate Revision Number and Date / 00 / --

Certificate Period / 3 Years

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

ISO 13485 KIOSCERT CERTIFICATE

KIOSCERT CERTIFICATION SERVICES LIMITED

Approval

KIOSCERT CERTIFICATION SERVICES LIMITED
KIOSCERT
CERTIFICATE

KIOSCERT CERTIFICATION SERVICES LIMITED
24 Brookdale London England N11 1BL
Phone : +44 077 486 18146
Web : www.kioscert.co.uk E mail : info@kioscert.co.uk | support@kioscert.co.uk
Certificate validity information **www.kioscert.co.uk** you can check at.
Company Registered in England and Wales with Company Number 14284313

KIOSCERT

KIOSCERT
CERTIFICATE

CERTIFICATE

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 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

Certificate First Issue Date / 21.03.2022

Certificate Validity Date / 20.03.2026

Certificate Release Date / 19.03.2025

Certificate No / GMP-22-2103-PIL

Certificate Revision Number and Date / 00 / --

Certificate Period / 3 Years

GMP KIOSCERT CERTIFICATE

KIOSCERT CERTIFICATION SERVICES LIMITED

Approval

KIOSCERT CERTIFICATION SERVICES LIMITED
24 Brookdale London England N11 1BL
Phone : +44 077 486 18146
Web : www.kioscert.co.uk E mail : info@kioscert.co.uk | support@kioscert.co.uk
Certificate validity information **www.kioscert.co.uk** you can check at.
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.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

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
e-Posta: halkla.iliskiler@titck.gov.tr İnternet Adresi: https://www.titck.gov.tr
Kep Adresi: titck@hs01.kep.tr

CERTIFICATE

NTA İMPLANT GRUP SANAYİ TİCARET ANONİM ŞİRKETİ

MEHMETÇİK MAH. 1241 SOK. NO:4
MURATPAŞA / ANTALYA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 9001:2015

The Quality Management System is applicable to:
Kalite Yönetim Sistemi:

DESING, DEVELOPMENT, PRODUCTION DISTRIBUTION AND SALES OF DENTAL IMPLANT SYSTEM (ENDOSSEOUS DENTAL IMPLANT, ENDOSSEOUS DENTAL IMPLANT ABUTMENT, ENDOSSEOUS DENTAL IMPLANT ACCESSORIES, SURGICAL INSTRUMENTS, SURGICAL KITS, DIGITAL INTRAORAL SCANNER SYSTEM)

DENTAL İMPLANT SİSTEMİNİN (ENDOSSEOUS DENTAL İMPLANT, ENDOSSEOUS DENTAL İMPLANT ABUTMENT, ENDOSSEOUS DENTAL İMPLANT AKSESUARLARI, CERRAHİ ALETLER, CERRAHİ KİTLER, DİJİTAL INTRAORAL AĞIZ İÇİ TARAYICI SİSTEM) TASARIMI, GELİŞTİRİLMESİ, ÜRETİMİ, DAĞITIMI VE SATIŞI

Certificate Number: QMS-006495
Belge Numarası: QMS-006495

Initial Certification Date: 07.03.2025
İlk Belgelendirme Tarihi: 07.03.2025

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 06.03.2026
Belge Geçerlilik Tarihi: 06.03.2026

IQR Sertifikasyon Onayı

ACCREDITED
Management Systems
Certification Body
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com

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. Production and Sales of Mask and Coverall.

Certificate No : A-231031
Release Date : 17.10.2023
Last Issue Date : 16.10.2024
Expiry Date : 16.10.2025
Period Exp. Date : 16.10.2026

WQR International Certification Ltd.
Director

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

CERTIFICATE

NTA İMPLANT GRUP SANAYİ TİCARET ANONİM ŞİRKETİ

MEHMETÇİK MAH. 1241 SOK. NO:4
MURATPAŞA / ANTALYA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 13485:2016

Medical Devices-Quality Management System is applicable to:
Tıbbi Cihazlar Kalite Yönetim Sistemi

DESING, DEVELOPMENT, PRODUCTION DISTRIBUTION AND SALES OF DENTAL IMPLANT SYSTEM (ENDOSSEOUS DENTAL IMPLANT, ENDOSSEOUS DENTAL IMPLANT ABUTMENT, ENDOSSEOUS DENTAL IMPLANT ACCESSORIES, SURGICAL INSTRUMENTS, SURGICAL KITS, DIGITAL INTRAORAL SCANNER SYSTEM)

DENTAL İMPLANT SİSTEMİNİN (ENDOSSEOUS DENTAL İMPLANT, ENDOSSEOUS DENTAL İMPLANT ABUTMENT, ENDOSSEOUS DENTAL İMPLANT AKSESUARLARI, CERRAHİ ALETLER, CERRAHİ KİTLER, DİJİTAL INTRAORAL AĞIZ İÇİ TARAYICI SİSTEM) TASARIMI, GELİŞTİRİLMESİ, ÜRETİMİ, DAĞITIMI VE SATIŞI

Certificate Number: 2025/MDQMS/000886 **Initial Certification Date: 07.03.2025**
Belge Numarası: 2025/MDQMS/000886 **İlk Belgelendirme Tarihi: 07.03.2025**

Certification Period: 3 Years **Certificate Validity Date: 06.03.2026**
Belgelendirme Periyodu: 3 Yıl **Belge Geçerlilik Tarihi: 06.03.2026**

IQR Sertifikasyon Onayı

ACCREDITED
Management Systems
Certification Body
MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com