



NTA<sup>®</sup> IMPLANT

*Certificate*

**NTA  
IMPLANT  
CONFIDENCE  
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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

**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** : Sterile Dental Implant  
Non-Sterile Dental Abutment&Accessories

*\*Detailed information is in the attached device list.*

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



# 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 <i>*Should be specified only for class IIb and class III devices.</i>
<b>Sterile Dental Implant</b>			
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 chewing function.
NTA Implant-Tissue Level			
NTA Implant Spure			
NTA Hybrid Implant			
<b>Non-Sterile Dental Abutment</b>			
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 A.Ş. is a Notified Body under the (EU) 2017/745 Medical Device Regulation. Notified Body No: 2292



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 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.*



  
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





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 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 / --

*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.*



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Company Registered in England and Wales with Company Number 14284313



## 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  
*[Signature]*



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 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 / --

*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.*



  
Approval

KIOSCERT CERTIFICATION SERVICES LIMITED  
24 Brookdale London England N11 1BL  
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Company Registered in England and Wales with Company Number 14284313



**KIOSCERT**



## 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

Muhteşem Gökhan Yücel  
Head of Notified Body

24 September 2020, Istanbul, Turkey

CERTIFICATE



T.C.  
SAĞLIK BAKANLIĞI  
Türkiye İlaç ve Tıbbi Cihaz Kurumu



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

11.07.2024

NTA İMPLANT TİCARET VE SANAYİ LTD. ŞTİ.  
Tahılpaşarı 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 "In 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 In Vitro Tanı Amaçlı Tıbbi Cihaz Yönetmeliğinde söz konusu değişiklikler 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

Bu belge, güvenli elektronik imza ile imzalanmıştır.

Belge Doğrulama Kodu: ZW56ak1Uz1AxM0FyYnUyQ3NRZ1AxZ1Ax

Belge Takip Adresi: <https://www.turkiyc.gov.tr/saglik-titck-cbys>

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](mailto:halkla.iliskiler@titck.gov.tr) İnternet Adresi: <https://www.titck.gov.tr>  
Kep Adresi: [titck@hs01.kep.tr](mailto:titck@hs01.kep.tr)





# 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**

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**



**ACCREDITED**  
Management Systems  
Certification Body  
MSCB-196



**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 according 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](http://www.KingCert.com) . The certificate is property of King Cert International Certification Ltd. and shall be returned if so requested.



# 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 Intraony Dental Implants and Abutments*



**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**

**ACCREDITED**  
**CERTIFICATION BODIES**  
**EN ISO/IEC 17021**



# 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.*



**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**