



# CERTIFICATE



This is to certify that the company

## TRINON Titanium GmbH

Augartenstraße 1  
76137 Karlsruhe  
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certificate and applicable country-specific requirements:

Design, manufacturing and distribution of Bone Plate, Driver Extractor Bone Nail/Pin, Distractor, Abutment, Implant bone grafting, Implant endosseous, Plate Bone, Set bone plate, Plate & Screw Fixation Bone, Implant fixation device condylarplate, Cranioplasty plate, Bone plate skull, Nail/plate introducer, Matrix Dental, Instrument dental, Dental Instruments set, Screwdriver skull, Surgical Scalpel blades, disposable scalpels and orthodontic appliances for correction of jaw and tooth malocclusions.

**-AUS (a), CND, JPN, USA (a,b,c,d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016 (MDSAP Audit Model Edition 2)

including country-specific requirements as shown in the scope  
(full references are listed in the annex)

Certificate registration no.	490666 MDSAP16
Certificate unique ID	170731453
Effective date	2019-05-13
Expiry date	2022-05-12
Frankfurt am Main	2019-05-13



### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Szymon Kurdyn  
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

**DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.**  
Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



**Annex to certificate**  
**Certificate registration No.: 490666 MDSAP16**  
**Certificate unique ID: 170731453**  
**Effective date: 2019-05-13**



## **TRINON Titanium GmbH**

Augartenstraße 1  
76137 Karlsruhe  
Germany

### **Audited site**

**TRINON Titanium GmbH**  
Augartenstraße 1  
76137 Karlsruhe  
Germany

### **DUNS No., site scope and country-specific requirements**

Design, manufacturing and distribution of Bone Plate, Driver Extractor Bone Nail/Pin, Distractor, Abutment, Implant bone grafting, Implant endosseous, Plate Bone, Set bone plate, Plate & Screw Fixation Bone, Implant fixation device condylarplate, Cranioplasty plate, Bone plate skull, Nail/plate introducer, Matrix Dental, Instrument dental, Dental Instruments set, Screwdriver skull, Surgical Scalpel blades, disposable scalpels and orthodontic appliances for correction of jaw and tooth malocclusions.

**-AUS (a), CND, JPN, USA (a,b,c,d)**

**DUNS No.: 312818750**

**Micro-Fix OÜ**  
Linda 12  
20309 Narva  
Estonia

Design, manufacturing, quality control of Bone Plate, Driver Extractor Bone Nail/Pin, Distractor, Abutment, Implant bone grafting, Implant endosseous, Plate Bone, Set bone plate, Plate & Screw Fixation Bone, Implant fixation device condylarplate, Cranioplasty plate, Bone plate skull, Nail/plate introducer, Matrix Dental, Instrument dental, Dental Instruments set, Screwdriver skull, Surgical Scalpel blades, disposable scalpels and orthodontic appliances for correction of jaw and tooth malocclusions.

**-AUS (a), CND, JPN, USA (a,b,c,d)**

**DUNS No.: 647322994**



**Annex to certificate**  
**Certificate registration No.: 490666 MDSAP16**  
**Certificate unique ID: 170731453**  
**Effective date: 2019-05-13**



## **TRINON Titanium GmbH**

Augartenstraße 1  
76137 Karlsruhe  
Germany

### **Audited site**

### **DUNS No., site scope and country-specific requirements**

**Micro-Fix OÜ**  
Linda 6  
20309 Narva  
Estonia

Manufacturing of Bone Plate, Driver Extractor Bone Nail/Pin, Distractor, Abutment, Implant bone grafting, Implant endosseous, Plate Bone, Set bone plate, Plate & Screw Fixation Bone, Implant fixation device condylarplate, Cranioplasty plate, Bone plate skull, Nail/plate introducer, Matrix Dental, Instrument dental, Dental Instruments set, Screwdriver skull, Surgical Scalpel blades, disposable scalpels and orthodontic appliances for correction of jaw and tooth malocclusions.  
**-AUS (a), CND, JPN, USA (a,b,c,d)**  
**DUNS No.: 647322994**

**Micro-Fix OÜ**  
Linda 8  
20309 Narva  
Estonia

Manufacturing of Bone Plate, Driver Extractor Bone Nail/Pin, Distractor, Abutment, Implant bone grafting, Implant endosseous, Plate Bone, Set bone plate, Plate & Screw Fixation Bone, Implant fixation device condylarplate, Cranioplasty plate, Bone plate skull, Nail/plate introducer, Matrix Dental, Instrument dental, Dental Instruments set, Screwdriver skull, Surgical Scalpel blades, disposable scalpels and orthodontic appliances for correction of jaw and tooth malocclusions.  
**-AUS (a), CND, JPN, USA (a,b,c,d)**  
**DUNS No.: 647322994**

**Micro-Fix OÜ**  
Suur-Aguli 7  
20309 Narva  
Estonia

Cleaning and packaging of implant endosseous.  
**-AUS (a), CND, JPN, USA (a,b,c,d)**  
**DUNS No.: 647322994**



**Annex to certificate**  
**Certificate registration No.: 490666 MDSAP16**  
**Certificate unique ID: 170731453**  
**Effective date: 2019-05-13**

## **TRINON Titanium GmbH**

Augartenstraße 1  
76137 Karlsruhe  
Germany

### **Full references of country-specific requirements of MDSAP participating Regulatory Authorities**

<b>Abbreviation</b>	<b>Jurisdiction</b>	<b>Reference</b>
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure  (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821