

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**11516-2017-CE-NOR-NA-PS Rev. 2.0**

Project No.:  
**PRJC-501875-2014-PRC-NOR**

Valid Until:  
**01 February 2023**

This is to certify that the quality system of:

### **Ditron Dental Ltd.**

2 Haofe St.  
7815001 Ashkelon  
Israel

For design, production and final product inspection/testing of:

### **Dental Implants & Abutments**

Has been assessed with respect to:

**The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:  
**Høvik, 15 June 2018**



For:  
**DNV GL NEMKO PRESAFE AS**

**Mariann Jeremiassen**

Management Representative

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**11516-2017-CE-NOR-NA-PS Rev. 2.0**

Project No.:  
**PRJC-501875-2014-PRC-NOR**

Valid Until:  
**01 February 2023**

### Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

### Certificate history:

Revision	Description	Issue Date
	Replaces certificate EU1402401Rev 1.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-10-26
1.0	Recertification and Scope extension	2018-06-12
2.0	<b>Corrections to text</b>	<b>2018-06-15</b>

### Products covered by this Certificate:

Product Description	Product Name	Class
Sterile dental implant	Molecular Precision Implant (MPI), Diameter 3.30 to 6.0 mm, length 6.0 to 16.0 mm Cylindrical Precision Implant (CPI), Diameter 3.75 to 6.0 mm, length 8.0 to 16.0 mm One Piece Precision Implant (OPI), Diameter 3.0 to 3.3 mm, length 10.0 to 16.0 mm Ultimate Implant (ULT), Diameter 3.50 to 6.0 mm, length 7.0 to 16.0 mm Advanced Precision Implant (API), Diameter 3.30 to 6.0 mm, length 8.0 to 16.0 mm	IIb
Non sterile Dental Abutments	Healing cap Healing abutment 2mm to 7 mm Impression coping analog and transfer Straight and anatomic abutments Angulated and anatomic angulated abutments Temporary abutments Plastic sleeve set Casting abutments Screw retained abutments Bar retained abutments Straight multi-unit abutments	IIb

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**11516-2017-CE-NOR-NA-PS Rev. 2.0**

Project No.:  
**PRJC-501875-2014-PRC-NOR**

Valid Until:  
**01 February 2023**

	Angulated multi-unit abutment Ball attachment abutment Liberator restoration attachment Liberator retention processing package Long Angulated abutment 15° to 25°, 11.5mm. length, Hex rotated by 30°	
<b>Sterile Cover screw</b>	<b>Cover screw</b>	<b>IIb</b>

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
Ditron Dental Ltd.	2 Haofe St., 7815001, Ashkelon, Israel

### EU Representative

MEDNET GmbH, Borkstrasse 10,48163 Munster, Germany, Phone: +49 251 32266 01

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**11516-2017-CE-NOR-NA-PS Rev. 2.0**

Project No.:  
**PRJC-501875-2014-PRC-NOR**

Valid Until:  
**01 February 2023**

### Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

### Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate