

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**247963-2017-CE-NOR-NA-PS Rev. 0.0**

Project No.:  
**PRJC-472044-2013-MSL-NOR**

Valid Until:  
**01 March 2020**

This is to certify that the quality system of:

**Polident d.o.o**  
**Volcja Draga 42**  
**5293 Volcja Draga**  
**Slovenia**

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

**Medical devices for dentistry**

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, 16 October 2017**



For:  
**DNV GL NEMKO PRESAFE AS**

Sholeh Gheissar

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.:  
**247963-2017-CE-NOR-NA-PS Rev. 0.0**

Project No.:  
**PRJC-472044-2013-MSL-NOR**

Valid Until:  
**01 March 2020**

### 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
0.0	Replaces Nemko (NB 0470) certificate No. EU1101415 following transfer of notified body functions to DNV GL Nemko Presafe AS (NB 2460). Removal of products from certificate.	2017-10-16

### Products covered by this Certificate:

Product Description	Product Name	Class
Synthetic polymer teeth	Primodent, Type 1 (anterior) Primodent, Type 2 (posterior) Cross Linked 2, Type 1 (anterior) Cross Linked 2, Type 2 (posterior) Basic, Type 1 (anterior) Basic, Type 2 (posterior) REF-LINE, Type 1 (anterior) REF-LINE, Type 2 (posterior) TREND GD DENT, Type 1 TREND GD DENT, Type 2	Ila
Denture base polymer materials	Polihot Policold K-30 S Polirepar S	Ila
Denture base resin heat-cured	PINK CAD-CAM DISC	Ila
Denture base resin	Poliflow	Ila
Orthodontic polymer material	Ortopoli	Ila
Cold-curing acrylic resin material for temporary crowns and	Politemp	Ila

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**247963-2017-CE-NOR-NA-PS Rev. 0.0**

Project No.:  
**PRJC-472044-2013-MSL-NOR**

Valid Until:  
**01 March 2020**

bridges		
Saliva aspirators	Disposable Dental Saliva Ejectors	Ila
Casting alloys	Polialloy NP Co-Cr Polialloy NP Ni-Cr Polialloy Partial NP Co-Cr	Ila
Polymer discs for fabrication of temporary crowns/bridges/test framework	PMMA CAD/CAM disc	Ila
Dental amalgam alloy	Amalgam Polident "Non gamma 2"	Ila

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
Polident d.o.o	Volcja Draga 42,5293,Volcja Draga,Slovenia

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**247963-2017-CE-NOR-NA-PS Rev. 0.0**

Project No.:  
**PRJC-472044-2013-MSL-NOR**

Valid Until:  
**01 March 2020**

### 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