

# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
10000395105-PA-NA-SVK Rev.1.0

Project No.:  
PRJC-91202-2008-PRC-SVK

Valid Until:  
27 May 2024

This is to certify that the quality system of:

### **DIPLOMAT DENTAL s.r.o**

Vrbovská cesta 17, 921 01 Piešťany Slovak Republic

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

Has been assessed with respect to:

**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN  
ANNEX II EXCLUDING SECTION 4 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, 11 November 2020**

For:  
**DNV GL PRESAFE AS**  
**Notified Body No.: 2460**

  
**Mariann Jeremiassen**

The certificate is digitally verified by blockchain technology. For more info, see [www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



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## 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	Correction of product names from ADEPT, CONSUL, LUX to DIPLOMAT ADEPT, DIPLOMAT CONSUL, DIPLOMAT LUX. Adding new brand names (MODEL PRO 500, MODEL PRO 600, MODEL PRO 700, MODEL PRO 800), previously in the certificate n.:10426-2017-CE-CZS-NA-PS	2020-09-16
1.0	Adding new brand names TYGI 400 L, TYGI 600 L, TYGI 400 B, TYGI 600 B, MODEL ONE 100, TYGI 200 B, MODEL ONE 200, TYGI 200 L.	2020-11-11

Products covered by this Certificate:

Product Description	Product Name	Class
Dental units	<p>DIPLOMAT ADEPT: DA 270 (TYGI 300 L, TYGI 400 L, MODEL PRO 600), DA 280 (TYGI 350 L), DA 370 (TYGI 500 L, TYGI 600 L, MODEL PRO 800), DA 380 (TYGI 550 L)</p> <p>DIPLOMAT CONSUL: DC 310 (TYGI 300 B, TYGI 400 B, MODEL PRO 500), DC 350 (TYGI 500 B, TYGI 600 B, MODEL PRO 700), DC 240, DC 290 (MODEL ONE 100, TYGI 200 B)</p> <p>DIPLOMAT LUX: DL 210 (TYGI 350 B), DL 270, DL 290 (MODEL ONE 200, TYGI 200 L), DL 320 (TYGI 550 B), DL 330, DL 340, DL 380</p>	IIa

The complete list of devices is filed with the Notified Body

## Sites covered by this certificate

Site Name	Address
DIPLOMAT DENTAL s.r.o.	Vrbovská cesta 17, 92101 Piešťany, Slovak Republic

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## 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