



# DNV BUSINESS ASSURANCE

## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

Certificate No. 77431-2010-CE-CZS 6.0  
This Certificate consists of 3 pages

*This is to certify that the Quality Management 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 Treatment Sets with accessories**

*has been assessed with respect to*  
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4  
(Module H) of Council Directive 93/42/EEC on Medical Devices, as amended,  
and found to comply

*Further details are given overleaf*

*Place and date:*  
Høvik, 16 April 2015

*This Certificate is valid until:*  
**11 May 2020**

For DNV GL BUSINESS ASSURANCE  
NORWAY AS.



Aud Løken Eiklid  
Certification Manager

Notified Body No.:  
0434

Cecilie Gudesen Torp  
Technical Reviewer

*This Certificate has been digitally signed. See [www.dnv.com/digitalsignatures](http://www.dnv.com/digitalsignatures) for more info*

**Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.**

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300 000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 77431-2010-CE-CZS  
 Rev. No.: 6.0  
 Project No.: PRJC-91202-2008-PRC-SVK

## Jurisdiction

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

## Certificate history

Revision	Description	Issue Date
	Original certificate	2005-05-11
	Recertification	2010-05-11
1.0	Added new product/ editorial changes	2011-11-30
2.0	Change of Company name	2012-11-01
3.0	Removing the original variants DA 130, DA 170, DA 270, DA 280 from 2009 and adding of new variants: DA 170, DA 130, DA 270, DA 280 from 2013	2014-02-11
4.0	Adding new models – Dental instruments	2014-02-11
5.0	Deleting the product DIPLOMAT ECONOMY and the variants DL 250 and DA 130 (DA220)	2014-08-19
<b>6.0</b>	<b>Recertification</b>	<b>2015-05-11</b>

## Products covered by this Certificate

Product Description	Product	Class
Dental Treatment Sets with accessories	DIPLOMAT ADEPT <ul style="list-style-type: none"> <li>▪ DA 110 A, DA 120, DA 140</li> <li>▪ DA 170 (TYGI 100 L), DA 130 (TYGI 150 L), DA 230, DA 240, DA 290, DA 320, DA 330</li> <li>▪ DA 280 (TYGI 350 L), DA 270 (TYGI 300 L)</li> <li>▪ DA 370 (TYGI 500 L), DA 380 (TYGI 550 L)</li> </ul> DIPLOMAT CONSUL <ul style="list-style-type: none"> <li>▪ DC 170 (TYGI 100 B), DC 180 (TYGI 150 B)</li> <li>▪ DC 310 (TYGI 300 B), DC 270, DC 280, DC 290</li> <li>▪ DC 350 (TYGI 500 B)</li> </ul> DIPLOMAT LUX <ul style="list-style-type: none"> <li>▪ DL 210 (TYGI 350 B), DC 220, DC 230, DC 240</li> <li>▪ DL 320 (TYGI 550 B), DL 330, DL 340, DL 270, DL 280, DL 290, DL 370, DL 380</li> </ul>	IIa



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Dental Instruments	High Speed Handpieces	IIa
Brand name:	Air motor	
DENSIM	Handpieces	

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, 921 01 Piešťany, Slovak Republic

#### 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 the local DNV Office of any intended updating of the quality system and DNV 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 DNV 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 DNV.

#### END OF CERTIFICATE

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## LIST OF MODELS OF MEDICAL DEVICE

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**List of models of Medical Device to the Certificate No.:** 77431-2010-CE-CZS Rev. 6.0

**Manufacturer:** DIPLOMAT DENTAL s.r.o.  
Vrbovská cesta 17  
921 01 Piešťany, Slovak Republic

**Product group:** Dental Treatment Sets with accessories

The Certificate referred to above covers the following devices:

### Dental Instruments DENSIM (brand name):

#### High Speed Handpieces

- High Speed Handpieces without light / with light and quick couple / with quick couple and mini Head
  - VIENNA, VERONA
  - MONACO Lux, MONTREAL Lux
  - TORONTO Lux
  - MONACO S Lux, MONTREAL S Lux
  - TORONTO S Lux

#### Air motor

- WELLINGTON

#### Handpieces

- Straight Handpiece / Contra Angel Handpiece / Contra Angel Handpiece with light / Contra Angel Head
  - DUBLIN P 1:1, DUBLIN U 1:1
  - SYDNEY P 1:1, SYDNEY U 1:1
  - PARIS P 1:1, PARIS U 1:1
  - MADRID P 1:1, MADRID U 1:1
  - DUBLIN U 1:1 Lux, SYDNEY U 1:1 Lux
  - PARIS U 1:1 Lux, MADRID U 1:1 Lux
  - DUBLIN U 1:5, DUBLIN U 1:5 Lux
  - PARIS U 1:5, PARIS U 1:5 Lux
  - MADRID U 1:5, MADRID U 1:5 Lux
  - DUBLIN HEAD, PARIS HEAD

16 April 2015

DNV GL Business Assurance  
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Iva Pavličková  
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