

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

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

For DNV GL BUSINESS ASSURANCE Norway AS. NORWEGIAN ACCREDITATION This Certificate is valid until:

11 May 2020

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Aud Løken Eiklid Certification Manager CE

Notified Body No.: 0434

Cecilie Gudesen Torp

Technical Reviewer

This Certificate has been digitally signed. See www.diw.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 subsidieries, 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

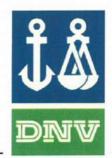
Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

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 |
| 6.0 | Recertification | 2015-05-11 |

Products covered by this Certificate

| Product Description | Class |
|--|--|
| Dental Treatment Sets with accessories | IIa 50 L), 330 00 L) 50 L) 50 B) 0, DC 290 DC 240 DL 270, |



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| Dental Instruments Brand name: | High Speed Handpieces | IIa |
|--------------------------------|-----------------------|-----|
| | 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

LIST OF MODELS OF MEDICAL DEVICE

List of models of Medical Device

77431-2010-CE-CZS Rev. 6.0

to the Certificate No.:

DIPLOMAT DENTAL s.r.o.

Vrbovská cesta 17

921 01 Piešťany, Slovak Republic

Product group:

Manufacturer:

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 Slovakia s.r.o. Sabinovská 8 SK - 821 02 Bratislava IČ: 35849509 IČ DPH: SK 2021705268

Iva Pavlíčková
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