

# DNV BUSINESS ASSURANCE

## PRODUCTION QUALITY MANAGEMENT CERTIFICATE

Certificate No. 72262-2010-CE-CZS-NA Rev. 5.0  
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 production and final product inspection/testing of*

### **Dental Medical Devices**

*has, on a voluntary basis, been assessed with respect to*

the requirements for documentation specified in Annex VII, section 3 of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

*Further details are given overleaf*

*Place and date:*

Høvik, 20 April 2015

*This Certificate is valid until:*

**03 March 2020**

For DNV GL BUSINESS ASSURANCE  
NORWAY AS.



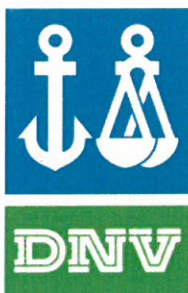
Aud Løken Eiklid  
*Certification Manager*

Angela Lanna  
*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.: 72262-2010-CE-CZS-NA  
Rev. No.: 5.0  
Project No.: PRJC-219665-2010-PRC-SVK

### Certificate history

Revision	Description	Issue Date
	Original Certificate	2010-03-03
1.0	Extension of scope – new devices added	2010-05-07
2.0	Change of Company name	2012-11-01
3.0	Adding a new model	2014-02-11
4.0	Deleting the model DIPLOMAT DM 10E	2014-08-19
<b>5.0</b>	<b>Recertification</b>	<b>2015-03-03</b>

### Products covered by this Certificate

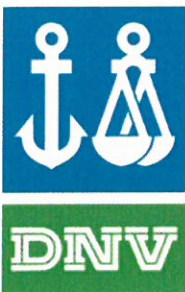
Product Description	Product name and type designation	Class
Dental Light	<ul style="list-style-type: none"><li>▪ XENOS</li><li>▪ SIRIUS DS 1</li></ul>	I
Dental Chair	<ul style="list-style-type: none"><li>▪ DIPLOMAT DM 20 (TYGI DM 20), DE 20 (TYGI DE 20)</li><li>▪ DE 20 LIFT (<i>for Russian speaking territories DE 30</i>)</li></ul>	I
Dental Stool	<ul style="list-style-type: none"><li>▪ D 10L</li></ul>	I

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





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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 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.

**END OF CERTIFICATE**