



3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-056

DIPLOMAT DENTAL s. r. o.

Vrbovská cesta 17, 921 01, Piešťany, Slovakia
SRN No.: SK-MF-000002562

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

DENTAL UNITS

Brand name: DIPLOMAT

Intended purpose: Annex II

MD class IIa

(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the Technical Documentation Assessment Report No. MDR413_2024 from 04.10.2025, Clinical Evaluation Report No. MDR413_2024 from 03.11.2025 and Audit Report No. MDR413_2024 from 15.11.2025. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **21.11.2025**
Valid until: **21.11.2030**
First issue: **21.11.2025**
Revision: **00**
History: **Annex III**



3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 21.11.2025



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-056

issued for the company

DIPLOMAT DENTAL s. r. o.

Vrbovská cesta 17, 921 01, Piešťany, Slovakia

List of medical devices covered by the EU Quality Management System Certificate:

Medical device name	Brand Name	Models / Variants	Alternative trade names
DENTAL UNITS	DIPLOMAT	MODEL PRO 800	DA 370, TYGI 500 L, TYGI 600 L, DA 380, TYGI 550 L
		MODEL PRO 600	DA 270, TYGI 300 L, TYGI 400 L, DA 280, TYGI 350 L
		MODEL ONE 200	DA 170, DA 290, DL 290, TYGI 200 L, MODEL ALFA
		MODEL PRO 700	DC 350, TYGI 500 B, TYGI 600 B, DL 320, TYGI 550 B
		MODEL PRO 500	DC 310, TYGI 300 B, TYGI 400 B, DL 210, TYGI 350 B
		MODEL ONE 100	DC 170, DC180, DC 290, TYGI 200 B, MODEL ZERO

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Katarína Tomin Srdošová, PhD.
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Valid until 21.11.2030



**ANNEX II TO EU QUALITY MANAGEMENT SYSTEM
CERTIFICATE No. 2025-MDR/QS-056**

issued for the company

DIPLOMAT DENTAL s. r. o.

Vrbovská cesta 17, 921 01, Piešťany, Slovakia

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Dental unit is specified to support and position the patient and to administer necessary supply for instruments and for performing the dental treatment of the patient by the dentist.

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-056

issued for the company

DIPLOMAT DENTAL s. r. o.

Vrbovská cesta 17, 921 01, Piešťany, Slovakia

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2025-MDR/QS-056	21.11.2025	MDR413_2024	Initially issued certificate

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