



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

## EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-055

**EMS Handels Gesellschaft m.b.H.**

Jochingergasse 1, 2100 Korneuburg, Austria  
SRN No.: AT-MF-000002599

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:

**Electromyograph and Evoked Potential Equipment**

**Models: see Annex I**

**Intended purpose: see Annex II**

**MD class IIa / rule 10**

(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. MDR454\_2024 from 12.11.2025, Clinical Evaluation Report No. MDR454\_2024 from 12.11.2025 and Audit Report No. SK-0534/25 from 02.04.2025. 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: **12.11.2025**  
Valid until: **19.06.2029**  
First issue: **12.11.2025**  
Revision: **00**  
History: **see Annex III**



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

In Bratislava, Slovakia, 12.11.2025



**ANNEX I TO EU QUALITY MANAGEMENT SYSTEM  
CERTIFICATE No. 2025-MDR/QS-055**

issued for the company

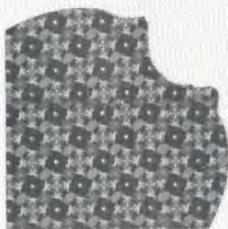
**EMS Handels Gesellschaft m.b.H.**

Jochingergasse 1, 2100 Korneuburg, Austria

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

MD Type	Models	Basic UDI-DI
Electromyograph and Evoked Potential Equipment	Surpass	912004097AX1CH
	Surpass LT	912004097BX1CN

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**Katarína Tomin Srdošová, PhD.**  
Director of NB 2265

In Bratislava, Slovakia, 12.11.2025  
Valid until 19.06.2029



**ANNEX II TO EU QUALITY MANAGEMENT SYSTEM  
CERTIFICATE No. 2025-MDR/QS-055**

issued for the company

**EMS Handels Gesellschaft m.b.H.**

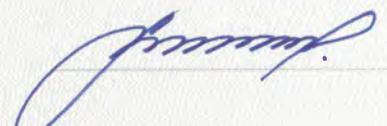
Jochingergasse 1, 2100 Korneuburg, Austria

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

The Surpass and the Surpass LT Electromyograph and Evoked Potential Equipment is used to diagnose and monitor neuromuscular disorders and to measure, record and analyse the electrical activity of muscles.

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**Katarína Tomin Srdošová, PhD.**  
Director of NB 2265

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# ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-055

issued for the company

**EMS Handels Gesellschaft m.b.H.**

Jochingergasse 1, 2100 Korneuburg, Austria

### Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2025-MDR/QS-055	12.11.2025	MDR454_2024	Initially issued certificate

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In Bratislava, Slovakia, 12.11.2025  
Valid until 19.06.2029

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