



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-045

MEDIATRADE s.r.o.

č.p. 34, 757 01 Poličná, Czech Republic
SRN No.: CZ-MF-000040050

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:

External pacemaker

Model/ variants: See Annex I

Intended purpose: Annex II

MD class IIb

(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. MDR407_2024 from 2026-06-29, Clinical Evaluation Report No. MDR407_2024 from 2026-06-29 and Audit Report No. MDR407_2024 from 2026-06-30. 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: **2026-07-07**
Valid until: **2031-07-07**
First issue: **2026-07-07**
Revision: **00**
History: **Annex III**

In Bratislava, Slovak Republic, 2026-07-07

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



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-045

issued for the company

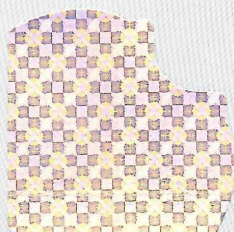
MEDIATRADE s.r.o.

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

Medical device	Type
External Pacemaker	EPG 10MO
	EPG 10B
	EPG 10M

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-07-07
Valid until 2031-07-07



ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-045

issued for the company

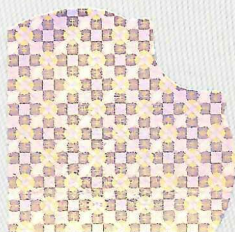
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Intended purpose of medical devices covered by the EU Quality Management System Certificate:

The EPG 10 External Pacemaker (models EPG 10MO, EPG 10B, and EPG 10M) is intended for temporary single-chamber atrial or ventricular pacing.

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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2026-MDR/QS-045

issued for the company

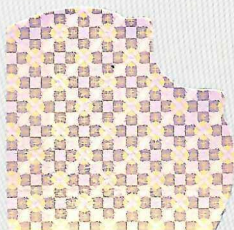
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Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2026-MDR/QS-045	2026-07-07	MDR407_2024	Initially issued certificate

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