

CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04

Medical devices - Quality management systems - Requirements for regulatory purposes



In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

Semecs s.r.o.
Hlavná 1797/62, 952 01 Vrábľe, Slovakia

with the location/site according to the annex

applies a management system in line with the above standard for the following scope

Production of electric and electronic control modules for medical applications.

Certificate Registration No. **AC090 MD/0023/3497/2025**
Audit Report No. PL3497_MD/2025

Valid from **14-05-2025**
Valid until **09-08-2026**

A handwritten signature in blue ink, appearing to read 'G. M. ...'.

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 14-05-2025

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

Visit https://listareferencyjna.tuv-nord.pl/Lista_Referencyjna.php to validate certificate authenticity.

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

www.tuv-nord.pl



AC 090

ANNEX

to Certificate Registration No.: **AC090 MD/0023/3497/2025**

issued on 14-05-2025

Semecs s.r.o.
Hlavná 1797/62, 952 01 Vrábľe, Slovakia

Certificate Registration No.

AC090 MD/0023/3497/2025-000

Location

Semecs s.r.o.
Hlavná 1797/62, 952 01 Vrábľe, Slovakia

Scope

Production of electric and electronic control modules for medical applications.

- Semecs s.r.o.
Hala 6 Horný Ohaj 467,
95201 Vrábľe, Slovakia

Internal processes within the scope of certification.

End of the List



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 14-05-2025

Visit https://listareferencyjna.tuv-nord.pl/Lista_Referencyjna.php to validate certificate authenticity.

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

www.tuv-nord.pl



AC 090