



Certificate

No. Q5 112750 0002 Rev. 01

Holder of Certificate: **POWERFUL MEDICAL s.r.o.**

Bratislavská 81/37

931 01 Šamorín

SLOVAKIA

Certification Mark:



Scope of Certificate: **Design and development and distribution of SaMD for AI-powered diagnostics and treatment**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 112750 0002 Rev. 01

Report No.: 713273890_CN

Valid from: 2023-05-09

Valid until: 2025-04-25

Date, 2023-05-09

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **POWERFUL MEDICAL s.r.o.**
Bratislavská 81/37, 931 01 Šamorín, SLOVAKIA

Administrative Office

POWERFUL MEDICAL s.r.o.
Karadžičova 8, 821 08 Bratislava, SLOVAKIA

See Scope of certificate

Parameters: ./.