

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Trianect B.V.
Princetonlaan 6
Utrecht
3584 CB
The Netherlands

Holds Certificate Number:


MD 834627

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design and development, manufacturing, and services of medical device software (electroencephalography acquisition and analysis) for triage of stroke patients in the pre-hospital and hospital environment.

Design and development, manufacturing of a portable electroencephalograph device & headset.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2026-02-16

Latest Revision Date: 2026-02-16

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Page: 1 of 1



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