By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abtrace Limited
Paddington Works
8 Hermitage St
Paddington
London
W2 1BE
United Kingdom

Holds Certificate Number: MD 715694

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

Design and development, manufacture, installation and distribution of artificial intelligence-based software for the analysis of data to aid patient monitoring and medical decisions.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-01-21
Latest Revision Date: 2025-12-16

Effective Date: 2026-01-21
Expiry Date: 2029-01-20

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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