

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

FUSE-AI GmbH
Großer Burstah 46-48
Hamburg
20457
Germany

Holds Certificate Number:

MD 775713

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

Design, Development and Sale of Assistance AI based Medical Devices software in the area of radiological imaging for diagnosis of prostate cancer

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-09-14

Latest Revision Date: 2023-09-14

Effective Date: 2023-09-14

Expiry Date: 2026-09-13

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