

Summary of Technical Documentation (STED) The Ophtascan™ software

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Class of Medical Device: Class I by Rule 11 of Annex VIII, Medical Device Regulation – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

Manufacturer Information:

ONCOTECH NORDIC AB

Address: Vastra Ljungbyvagen 275

26651 Vejbystrand, Sweden

Phone:

+ 46 761 333 396

Email:

ar@oncotechservices.com

CEO:

Andre Rafnsson

Person Responsible for

Regulatory Compliance

(PRRC):

Andre Rafnsson

Regulatory Consultant(s):

Dragan Jovic Milos Ilic

EU Authorized

N/A

Representative:

These signatures demonstrate that this document has been compiled, evaluated and approved and that it is fully compliant and in conformity with requirements from regulations, applicable harmonized and international standards, applicable SOPs and Good Documentation Practices.

Author:

Dragan Jovic

Approver:

Andre Rafnsson

Signature:

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Signature:

Date:

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