

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Arcoma AB

Main Site: Annavägen 1

352 46, Växjö, Sweden

(FIN F000738)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A

to D)

The management system is applicable to:

Design, manufacture, installation and servicing of devices for X-ray equipment.

Certificate Number:

0078355-02

Initial Certification Date:

2018-07-16

Date of Certification Decision:

2024-06-25

Certification Effective Date:

2024-07-15

Certification Expiry Date:

2027-07-15





intertek



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