EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Arcoma AB

Annavägen 1, SE- 352 46 Växjö, Sweden

Manufacturer SRN: SE-MF-000012673

Scope:

Positioning devices for X-ray systems

Certificate Number:
28620148171

Revision:
00

Initial Certification Date:
2 May 2023

Certificate Decision Date:
2 May 2023

Certificate Issue Date:
2 May 2023

Certificate Expiry Date:
15 July 2027

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00203-01 ARCOMA AB Intuition**
Audit Report Reference	**Stage 1 audit ACTY-2022-543002**
	Stage 2 audit ACTY-2022-543003
	Special visit audit ACTY-2022-613380
	Special visit audit ACTY-2021-463575

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620148171

Revision:
00

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MDR – Decision Report

Certificate No: 28620148171
Date: 2 May 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Arcoma AB
Attn: Henrik Blomdahl
Annavägen 1
SE- 352 46 Växjö
Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2022-543002 CTYno	Växjö	Gabriel Johansson	19 – 20 Oct 2022
Stage 2 ACTY-2022-543003	Växjö	Gabriel Johansson	13 – 15 Dec 2022
Special Visit ACTY-2022-613380	Offsite	Gabriel Johansson	16 Jan 2023
Special Visit ACTY-2021-463575	Växjö	Gabriel Johansson	14 – 17 Mar 2023

Technical Documentation Report	Assessor Name	Assessment Date
FINAL TDAR_ARCOMA_TD00203-01_2023-03-27	Gavin McLaughlin	27 Mar 2023
Appendix 1_CEAR_Arcoma_TD00203-01_2023-02-28	Gavin McLaughlin	28 Feb 2023
Appendix 2_Technical Documentation Request for Additional Information_Arcoma_TD00203-01_2023-03-23	Gavin McLaughlin	23 Mar 2023

Scope of assessment

Positioning devices for X-ray systems, Class IIb

Result

1 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Valid from

2 May 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel

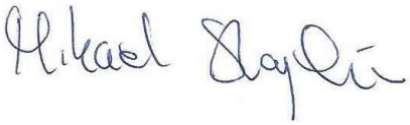
as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority (TD Assessment)



Mikael Hagelin
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Arcoma AB

Certificate number: 28620148171

Certificate valid from: 2023-05-02

Product List Issue Date:
02 May 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Positioning devices for X-ray systems			
Basic UDI-DI: 7350008750018P			
Arcoma 0072 - Precision	Class IIb Z11031101	Stationary medical device intended for positioning of patient, x-ray source and flat panel detectors in a clinical environment for x-ray examination of the human body.To be used in combination with a non-particular image aqcuisition system, and x-ray exposure chain.	2023-05-02
Basic UDI-DI: 7350008750058X			
Arcoma 0180 - Intuition	Class IIb Z11031101	Stationary medical device intended for positioning of patient, x-ray source and flat panel detectors in a clinical environment for x-ray examination of the human body.To be used in combination with a non-particular image aqcuisition system, and x-ray exposure chain.	2023-05-02
Basic UDI-DI: 7350008750218V			
0072CS - Overhead tube crane (OTC)	Class IIb Z11031180	The Overhead tube crane (OTC) is a stationary X-ray source holder intended for positioning and being the source of X-ray in radiographic imaging of various portions of the human body in a clinical environment. To be used in combination with a non-particular x-ray source	2023-05-02
0170 - Overhead tube crane (OTC)	Class IIb Z11031180	The Overhead tube crane (OTC) is a stationary X-ray source holder intended for positioning and being the source of X-ray in radiographic imaging of various portions of the human body in a clinical environment. To be used in combination with a non-particular x-ray source	2023-05-02

Brian Mather
Certification Authority, MDR
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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.