

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1169866-1

Organization: Ziehm Imaging GmbH
Lina-Ammon-Str. 10
90471 Nürnberg
Germany

Scope: Design and development, manufacture, distribution, installation and service
of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)

(see attachment for additional sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1083421-40
Effective date: 2021-09-14
Expiry date: 2024-09-13
Issue date: 2021-09-09




Dipl.-Ing. (FH) Daniele Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Ziehm Imaging GmbH Lina-Ammon-Str. 10 90471 Nürnberg Germany	Design and development, manufacture, distribution, installation and service of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)
/02	c/o Ziehm Imaging Austria GmbH Ziegelfeldstraße 10 3430 Tulln-Tulln an der Donau Austria	Distribution, installation and service of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)
/03	c/o Ziehm Imaging srl a Socio Unico VIA PAOLO BORSELLINO 22/24 42124 REGGIO EMILIA RE Italy	Distribution, installation and service of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)
/04	c/o Ziehm Imaging S.A.R.L 1 Allée de Londres 91140 Villejust France	Distribution, installation and service of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)

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The scope of certification also covers the following:

No.	Facility	Scope
/05	c/o Ziehm Imaging Oy Kumitehtaankatu 5 04260 Kerava Finland	Distribution of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)
/06	c/o Ziehm Imaging Oy Iso-Heikkiläntie 8 20200 Turku Finland	Storage of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)
/07	c/o Ziehm Imaging Oy Juhana Herttuan Puistokatu 21 20100 Turku Finland	Installation and service of mobile Radiographic/ Fluoroscopic Units (mobile C-arms)

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