

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Ziehm Imaging GmbH
Donaustr. 31
90451 Nürnberg
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, production, distribution
installation and service of mobile Radiographic/
Fluoroscopic Units (mobile C-arms)**
(see attachment for additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-09-14
Certificate Registration No.: SX 60132236 0001
An audit was performed. Report No.: 21229175 010
This Certificate is valid until: 2021-09-13

Certification Body



Date 2018-08-31



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60132236 0001
Report No.: 21229175 010

Organization: Ziehm Imaging GmbH
Donaustr. 31
90451 Nürnberg
Deutschland

Scope:

Sites included:

- Ziehm Imaging GmbH
Donaustr. 29, 90451 Nürnberg, Germany

Activities related to logistical processes
of mobile Radiographic/Fluoroscopic Units
(mobile C-arms) and their components

- Ziehm Imaging GmbH
Isarstr. 28, 90451 Nürnberg, Germany

Activities related to quality management,
regulatory affairs, sales and marketing

- Ziehm Imaging GmbH
Isarstr. 40, 90451 Nürnberg, Germany

Activities related to design and development, production
of mobile Radiographic/Fluoroscopic Units (mobile C-arms)

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60132236 0001
Report No.: 21229175 010

Organization: Ziehm Imaging GmbH
Donaustr. 31
90451 Nürnberg
Deutschland

Scope:

Sites included:

- Ziehm Imaging S.r.l. a Socio Unico
Via Paolo Borsellino 22/24
42124 Reggio Emilia, Italy

Activities related to distribution, installation and service
of mobile Radiographic/Fluoroscopic Units (mobile C-arms)

- Ziehm Imaging S.A.R.L.
1, Allée de Londres
91140 Villejust, France

Activities related to distribution, installation and service
of mobile Radiographic/Fluoroscopic Units (mobile C-arms)

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Registration No.: SX 60132236 0001
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Organization: Ziehm Imaging GmbH
Donaustr. 31
90451 Nürnberg
Deutschland

Scope:

Sites included:

- Ziehm Imaging Oy
Kumitehtaankatu 5
04260 Kerava, Finland

Activities related to distribution of mobile
Radiographic/Fluoroscopic Units (mobile C-arms)

- Ziehm Imaging Oy
Iso-Heikkiläntie 8
20200 Turku, Finland

Activities related to installation and service of
mobile Radiographic/Fluoroscopic Units (mobile C-arms)

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