EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60139362 0001

Report No.: 21229175 016

Manufacturer:
Ziehm Imaging GmbH
Donaustr. 31
90451 Nürnberg
Deutschland

Products: mobile Radiographic/Fluoroscopic Units (mobile C-arms)

(see attachment for sites included)

Replaces certificate, registration no.: HD 60103860 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-05-28

Date: 2019-05-28

Notified Body

Roland Gruber

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60139362 0001
Report No.: 21229175 016

Manufacturer: Ziehm Imaging GmbH
Donaustr. 31
90451 Nürnberg
Deutschland

Site included:

Ziehm Imaging GmbH
Isarstraße 40
90451 Nürnberg, Germany

Notified Body

Roland Gruber

Date: 2019-05-28

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle