

DECLARATION OF CONFORMITY

We

Ziehm Imaging GmbH

Donaustrasse 31

90451 Nuremberg

Germany

info@ziehm.com

declare on our sole responsibility that the medical devices stated below meet all the requirements of Directive 93/42/EEC and 2007/47/EC.

Generic product group: Mobile Radiographic / Fluoroscopic Units
(mobile C-arms)

Products:

alternative trade names are included

Ziehm 8000
Ziehm Vision
Ziehm Vision FD
Ziehm Vision FD Vario
Ziehm Vision FD Vario 3D
Ziehm Vision R
Ziehm Vision RFD
Ziehm Vision RFD 3D
Ziehm Solo
Ziehm Solo FD

examples of included options:

Ziehm Viewing Station
Remote Vision Center (RVC)
Remote Solo Center (RSC)
Position Control Center (PCC)

Classification: IIb according to 93/42/EEC, Annex IX

Conformity assessment procedure: Complete quality assurance system according to 93/42/EEC, Annex II (excluding 4)

Certificate No.: HD 60139362 0001,
valid until: May 26, 2024

Notified Body: TÜV Rheinland LGA Products GmbH,
Nuremberg, no. 0197

Validity: identical to validity of EC certificate

Nuremberg, **May 28th, 2019**



Klaus Hörndler

Managing Director & CEO

Nuremberg, **May 28th, 2019**



Stephan Dippold

Managing Director & CFO

Nuremberg, **May 28th, 2019**



Stefan Fiedler

Director Quality Management/RA