

DECLARATION OF CONFORMITY

We

Ziehm Imaging GmbH

Lina-Ammon-Strasse 10

90471 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 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 1169866-1,
valid until: May 26, 2024

Notified Body:

TÜV Rheinland LGA Products GmbH,
Nuremberg, no. 0197

Validity:

identical to validity of EC certificate

Nuremberg, **March 22nd, 2021**



Klaus Hörndler

Managing Director & CEO

Nuremberg, **March 22nd, 2021**



Stephan Dippold

Managing Director & CFO

Nuremberg, **March 22nd, 2021**



Stefan Fiedler

Director Quality Management/RA