EU Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	Ziehm Vision RFD 3D
Basic UDI-DI according to Part C of Annex VI	++EZIEZIEHMVISIONRFD3DK6
Intended Purpose	The Ziehm Vision RFD 3D is a mobile C-arm providing image data by means of a non-invasive x-ray technique during medical procedures and stores them temporarily. The Ziehm Vision RFD 3D is intended for use in all medical indications requiring fluoroscopy. The Ziehm Vision RFD 3D is intended for use to provide 2D and 3D image data.
Classification according to Annex VIII	IIb

Manufacturer	Ziehm Imaging GmbH Lina-Ammon-Strasse 10 D - 90471 Nuremberg
Single Registration Number according to Art. 31	DE-MF-000011027

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device(s) in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
We hereby ensure that the medical device(s) that is/are covered by the present declaration is/are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

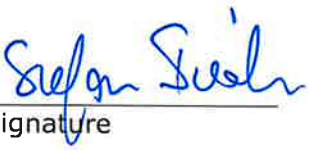
Digitally signed by Grabazei Alexandru
Date: 2026.07.06 13:16:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Applied Common Specifications

Common Specification (CS)	N/A, currently no Common Specification avaliable

Notified Body	TÜV Rheinland LGA Products GmbH
Registration Number	0197
Conformity assessment procedure performed	Annex IX Ch. 1 and Ch. 3
Certificate(s) issued	Certificate HZ 11698661 valid until 13.07.2028
CE marking since	2016
EU Declaration of Conformity is valid until	13.07.2028

Signed on behalf of Ziehm Imaging GmbH

Stefan Fiedler Principal Person Responsible for Regulatory Compliance (PRRC)	Nuremberg, 10.08.2023 Place, Date	 Signature

EU Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	Ziehm Vision RFD
Basic UDI-DI according to Part C of Annex VI	++EZIEZIEHMVISIONRFD35
Intended Purpose	The Ziehm Vision RFD is a mobile C-arm providing image data by means of a non-invasive x-ray technique during medical procedures and stores them temporarily.
Classification according to Annex VIII	IIb

Manufacturer	Ziehm Imaging GmbH Lina-Ammon-Strasse 10 D - 90471 Nuremberg
Single Registration Number according to Art. 31	DE-MF-000011027

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device(s) in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
We hereby ensure that the medical device(s) that is/are covered by the present declaration is/are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applied Common Specifications

Common Specification (CS)	N/A, currently no Common Specification avaliable

Notified Body	TÜV Rheinland LGA Products GmbH
Registration Number	0197
Conformity assessment procedure performed	Annex IX Ch. 1 and Ch. 3
Certificate(s) issued	Certificate HZ 11698661 valid until 13.07.2028
CE marking since	2006
EU Declaration of Conformity is valid until	13.07.2028

Signed on behalf of Ziehm Imaging GmbH

Stefan Fiedler Principal Person Responsible for Regulatory Compliance (PRRC)	Nuremberg, 10.08.2023 Place, Date	Stefan Fiedler Signature

EU Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	Ziehm Solo FD
Basic UDI-DI according to Part C of Annex VI	++EZIEZIEHMSOLOFDV4
Intended Purpose	The Ziehm Solo FD is a mobile C-arm providing image data by means of a non-invasive x-ray technique during medical procedures and stores them temporarily.
Classification according to Annex VIII	IIb

Manufacturer	Ziehm Imaging GmbH Lina-Ammon-Strasse 10 D - 90471 Nuremberg
Single Registration Number according to Art. 31	DE-MF-000011027

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device(s) in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
We hereby ensure that the medical device(s) that is/are covered by the present declaration is/are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applied Common Specifications

Common Specification (CS)	N/A, currently no Common Specification avaliable

Notified Body	TÜV Rheinland LGA Products GmbH
Registration Number	0197
Conformity assessment procedure performed	Annex IX Ch. 1 and Ch. 3
Certificate(s) issued	Certificate HZ 11698661 valid until 13.07.2028
CE marking since	2016
EU Declaration of Conformity is valid until	13.07.2028

Signed on behalf of Ziehm Imaging GmbH

Stefan Fiedler Principal Person Responsible for Regulatory Compliance (PRRC)	Nuremberg, 10.08.2023 Place, Date	Signature

EU Declaration of Conformity

according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Medical Device	Ziehm Vision FD
Basic UDI-DI according to Part C of Annex VI	++EZIEZIEHMVISIONFDH2
Intended Purpose	The Ziehm Vision FD is a mobile C-arm providing image data by means of a non-invasive x-ray technique during medical procedures and stores them temporarily.
Classification according to Annex VIII	IIb

Manufacturer	Ziehm Imaging GmbH Lina-Ammon-Strasse 10 D - 90471 Nuremberg
Single Registration Number according to Art. 31	DE-MF-000011027

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device(s) in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
We hereby ensure that the medical device(s) that is/are covered by the present declaration is/are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applied Common Specifications

Common Specification (CS)	N/A, currently no Common Specification avaliable

Notified Body	TÜV Rheinland LGA Products GmbH
Registration Number	0197
Conformity assessment procedure performed	Annex IX Ch. 1 and Ch. 3
Certificate(s) issued	Certificate HZ 11698661 valid until 13.07.2028
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Signed on behalf of Ziehm Imaging GmbH

Stefan Fiedler Principal Person Responsible for Regulatory Compliance (PRRC)	Nuremberg, 10.08.2023 Place, Date	Signature