



CERTIFICATE



This is to certify that the company

JENOPTIK Optical Systems GmbH

Göschwitzer Strasse 25
07745 Jena
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Design and Development, production and distribution of active non-implantable Imaging devices utilising non-ionizing radiation.

Design and Development, production and distribution of optomechatronic components for active non-implantable Imaging devices utilising non-ionizing radiation.

Design and Development and production of plastic optical components, optomechanical and optoelectronic assemblies for active non-implantable Imaging devices utilising non-ionizing radiation.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07

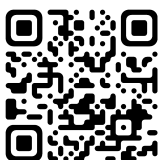
EN ISO 13485 : 2016 + AC : 2018

ISO 13485 : 2016

Certificate registration no.	490777 MP2016
Certificate unique ID	1000315325
Effective date	2026-05-06
Expiry date	2026-12-02
Frankfurt am Main	2026-05-06



DQS IS A MEMBER OF



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt a. M., Germany
The validity of the certification can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 490777 MP2016
Certificate unique ID: 1000315325
Effective date: 2026-05-06

JENOPTIK Optical Systems GmbH

Göschwitzer Strasse 25
07745 Jena
Germany

Location

Scope

516835

JENOPTIK Optical Systems GmbH
Göschwitzer Strasse 25
07745 Jena
Germany

Design and Development, production and distribution of active non-implantable Imaging devices utilising non-ionizing radiation.

366982

JENOPTIK Optical Systems GmbH
Am Sandberg 2
07819 Triptis
Germany

Design and Development and production of plastic optical components, optomechanical and optoelectronic assemblies for active non-implantable Imaging devices utilising non-ionizing radiation.

31621454

JENOPTIK Optical Systems GmbH
Groß-Berliner Damm 82A
12487 Berlin
Germany

Design and Development, production and distribution of optomechatronic components for active non-implantable Imaging devices utilising non-ionizing radiation.