



CERTIFICATE



This is to certify that the company



MEDAGENT International GmbH

Griesweg 47 78570 Mühlheim / Donau Germany

with the organizational units/sites as listed in the annex has implemented and maintains a Quality Management System.

Scope:

Design and development of software tools in the field of technical documentation of medical devices, training of medical device manufacturers in the field of development on quality management systems and regulatory requirements for medical devices.

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. 547430 MP2016

Certificate unique ID 1000129493 Effective date 2023-08-07 Expiry date 2026-08-06 Frankfurt am Main 2023-07-19



DOS IS A MEMBER OF





DQS Medizinprodukte GmbH

Sigrid Uhlemann Managing Director S. Kuelyn Szymon Kurdyn Product Manager





Annex to certificate

Certificate registration No.: 547430 MP2016

Certificate unique ID: 1000129493

Effective date: 2023-08-07

MEDAGENT International GmbH

Griesweg 47 78570 Mühlheim / Donau Germany

Location

Scope

547431

MEDAGENT International GmbH

Griesweg 47 78570 Mühlheim / Donau Germany Design and development of software tools in the field of technical documentation of medical devices, training of medical device manufacturers in the field of development on quality management systems and regulatory requirements for medical devices.

547432 MEDAGENT International GmbH

Tuttlinger Straße 24 78579 Neuhausen Germany Design and development of software tools in the field of technical documentation of medical devices, training of medical device manufacturers in the field of development on quality management systems and regulatory requirements for medical devices.