

Certificate

We hereby certify the company

IMPETUS Plastics Engineering GmbH
Mostardstraße 22
52062 Aachen
Germany

with the sites listed in the attachment the introduction and application of a

Quality management system according to EN ISO 13485

in the scope

Contract development of plastic components/assemblies for medical products and order-related production of plastic components/assemblies for testing purposes in the development of medical devices

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-04-26
Valid until 2028-04-25

Registration No. D1499200004
Report No. P25-00102-322750

Berlin, 2025-04-10



Certification Body

Sites included in the certification:

Location	Scope
IMPETUS Plastics Engineering GmbH Mostardstraße 22 52062 Aachen Germany	Contract development of plastic components/assemblies for medical products and order-related production of plastic components/assemblies for testing purposes in the development of medical devices
IMPETUS Plastics Engineering GmbH Bahnhofstraße 9 83043 Bad Aibling Germany	Contract development of plastic components/assemblies for medical products and order-related production of plastic components/assemblies for testing purposes in the development of medical devices
Temporary location: IMPETUS Plastics Engineering GmbH Heubergstraße 12g 83043 Bad Aibling Germany	Order-related production of plastic components/assemblies for testing purposes in the development of medical devices

Berlin, 2025-04-10

