

Certificate

mdc medical device certification GmbH
certifies that

IMPETUS Plastics Engineering GmbH
Mostardstraße 22
52062 Aachen
Germany

with the locations listed in the attachment

for 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**

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2022-04-26
Valid until	2025-04-25
Registration no.	D1499200002
Report no.	P21-01864-236226
Berlin	2022-04-25


Head of Certification Body



Attachment of the certificate

No. D1499200002

Date 2022-04-25

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Location	Scope
IMPETUS Plastics Engineering GmbH Bahnhofstraße 9, 83043 Bad Aibling	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 Mostardstraße 22, 52062 Aachen	
IMPETUS Plastics Engineering GmbH Heubergstraße 12g, 83043 Bad Aibling	Order-related production of plastic components/assemblies for testing purposes in the development of medical devices




Head of Certification Body