

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1809678-1

Organization: Medartis AG
Hochbergerstr. 60E
4057 Basel
Switzerland

Scope: Design and development, manufacture and distribution of craniomaxillofacial (CMF) and orthopedic implants, instruments, splints for the splinting of teeth as well as personalised CMF implants and orthopedic instruments, such as guides, positioning aids and bone models in 3D printing processes.
Design and development of medical image processing, simulation and design software.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1123609-40
Effective date: 2023-02-04
Expiry date: 2026-02-03
Issue date: 2023-01-28



[Signature]
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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Medartis AG Hochbergerstr. 60E 4057 Basel Switzerland	Design and development, manufacture and distribution of craniomaxillofacial (CMF) and orthopedic implants, instruments, splints for the splinting of teeth as well as personalised CMF implants and orthopedic instruments, such as guides, positioning aids and bone models in 3D printing processes.
/02	c/o Medartis GmbH Am Gansacker 10 79224 Umkirch Germany	Distribution of CMF and orthopedic implants and instruments as well as splints for the splinting of teeth.

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