

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1450174-1

Certificate Holder: BioCer Entwicklungs-GmbH
Ludwig-Thoma-Str. 36c
95447 Bayreuth
Germany

Scope: Design and development, manufacture and distribution of
haemostatic agents and adhesion prevention for surgical use,
biocompatible coatings and surgical mesh implants

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.: 1168996-100

Effective date: 2024-09-27

Expiry date: 2027-06-07

Issue date: 2024-09-27

Replaces certificate SX 1450174-1 issued on 05.06.2024

This certificate can be validated on <https://www.certipedia.com>

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜEV and TÜV are registered trademarks. Utilisation and application requires prior approval.

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1450174-1
Certificate Holder: BioCer Entwicklungs-GmbH
Ludwig-Thoma-Str. 36c
95447 Bayreuth
Germany

The scope of certification also covers the following sites:

| No. | Facility | Scope |
|-----|--|--|
| /01 | c/o BioCer Entwicklungs-GmbH Ludwig-Thoma-Str. 36c 95447 Bayreuth Germany | Administration |
| /02 | c/o BioCer Entwicklungs-GmbH Dieselstraße 15 95448 Bayreuth Germany | Design and development, manufacture and distribution of haemostatic agents and adhesion prevention for surgical use, biocompatible coatings and surgical mesh implants |

This certificate can be validated on <https://www.certipedia.com>