

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 1235887-1

Certificate Holder: Braunform GmbH
Unter Gereuth 7+14
79353 Bahlingen
Germany

Scope: Design and development, manufacture and distribution of injection molds, plastic components and stamping parts for medical devices

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.: 1170443-100

Effective date: 2025-01-24

Expiry date: 2028-01-05

Issue date: 2025-01-24

Replaces certificate SX 1235887-1 issued 2024-12-13



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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Braunform GmbH Unter Gereuth 7+14 79353 Bahlingen Germany	Design and development, manufacture and sales of injection molds for medical devices, design and development of plastic components for medical devices, manufacture of stamping parts for medical devices
/02	c/o Braunform GmbH Elsässer Str. 42 79346 Endingen Germany	Manufacture and sales of plastic components and stamping parts for medical devices

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