



## **CERTIFICATE**



This is to certify that the company

# Röchling

### **Röchling Medical Solutions SE**

Waldweg 16 98724 Neuhaus Germany

with the organizational units/sites as listed in the annex has implemented and maintains a **Quality Management System**.

#### Scope:

Development, manufacture and distribution of plastic systems for general non-active, non-implantable medical devices.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

**DIN EN ISO 13485:2021** 

EN ISO 13485:2016 / A11:2021

2025-11-03

ISO 13485:2016

Certificate registration no. 281477 MP2021
Certificate unique ID 1000255998
Effective date 2025-11-21
Expiry date 2028-11-20

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS IS A MEMBER OF





**DQS Medizinprodukte GmbH** 

Heinrich von Mettenheim Managing Director

Frankfurt am Main





**Annex to certificate** 

Certificate registration No.: 281477 MP2021

Certificate unique ID: 1000255998

Effective date: 2025-11-21

#### **Röchling Medical Solutions SE**

Waldweg 16 98724 Neuhaus Germany

Location Scope

544164

**Röchling Medical Solutions SE** Höchster Straße 100 64395 Brensbach Germany Development, manufacture and distribution of plastic systems for general non-active, non-implantable medical devices.

516463

**Röchling Medical Solutions SE**Waldweg 16
98724 Neuhaus am Rennweg
Germany

Development, manufacture and distribution of plastic systems for general non-active, non-implantable medical devices.