



# **CERTIFICATE**



This is to certify that the company



# SABEU GmbH & Co. KG

Detlev-Karsten-Rohwedder-Str. 10 37154 Northeim Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

#### Scope:

Contract assembly and contract production of plastic molded parts and surface membranes for general non-active, non-implantable medical devices and manufacturing, final inspection, packaging and storage of extruded plastic articles 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 : 2016 + AC : 2017-07

EN ISO 13485 : 2016 + AC : 2018

ISO 13485: 2016

Certificate registration no. 499578 MP2016

Certificate unique ID 1000145746 Effective date 2024-04-17 Expiry date 2027-04-16 Frankfurt am Main 2024-03-01

Deutsche Akkreditierungsstelle D-ZM-16021-01-00

DOS IS A MEMBER OF





**DQS Medizinprodukte GmbH** 

Sigrid Uhlemann Managing Director Szymon Kurdyn Product Manager

S. Kudyn





Annex to certificate

Certificate registration No.: 499578 MP2016

Certificate unique ID: 1000145746

Effective date: 2024-04-17

# **SABEU GmbH & Co. KG**

Detlev-Karsten-Rohwedder-Str. 10 37154 Northeim Germany

#### Location

## 500369 SABEU GmbH & Co. KG

Werk 1 Detlev-Karsten-Rohwedder-Str. 10 37154 Northeim Germany

## 515302 SABEU GmbH & Co. KG Werk 4

Anna-Vandenhoeck-Ring 24 37081 Göttingen Germany

#### Scope

Contract assembly and contract production of plastic molded parts and surface membranes for general non-active, non-implantable medical devices

Manufacturing, final inspection, packaging and storage of extruded plastic articles for general non-active, non-implantable medical devices.