



CERTIFICATE



This is to certify that the company

Ensinger O Ensinger GmbH

Rudolf-Diesel-Strasse 8 71154 Nufringen Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

Scope:

Development, production and sales of stock shapes, profiles, finished parts, composite materials and compounds made from thermosets and thermoplastics for medical applications (implants, components for medical equipment, dentistry)

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

000900 MP2016 Certificate registration no.

Certificate unique ID 1000135987 Effective date 2024-05-05 2027-05-04 Expiry date

Frankfurt am Main 2024-02-26



DOS IS A MEMBER OF





DQS Medizinprodukte GmbH

Managing Director

S. Kudyn





Annex to certificate

Certificate registration No.: 000900 MP2016

Certificate unique ID: 1000135987

Effective date: 2024-05-05

Ensinger GmbH

Rudolf-Diesel-Strasse 8 71154 Nufringen Germany

Location

302731 Ensinger GmbH Werk Nufringen Rudolf-Diesel-Straße 8 71154 Nufringen Germany

002992 Ensinger GmbH Werk Cham Wilfried-Ensinger-Straße 1 93413 Cham Germany

478095 Ensinger GmbH Werk Ergenzingen Mercedesstrasse 21 72108 Rottenburg Germany

Scope

Development, production and sales of stock shapes, profiles, finished parts, composite materials and compounds made from thermosets and thermoplastics for medical applications (implants, components for medical equipment, dentistry)

Development, production and sales of stock shapes, profiles, finished parts, composite materials and compounds made from thermosets and thermoplastics for medical applications (implants, components for medical equipment, dentistry)

Development, production and sales of moulded parts in injection moulding and composite materials made from thermosets and thermoplastics for medical applications (implants, components for medical equipment, dentistry)