EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Ortho Solutions GmbH

Eltastraße 2
78573 Wurmlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Rotating Instruments	Class IIa
Bone screws	Class IIb
Bone plates	Class IIb
Ring fixator	Class IIb

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	548484 MR2
Certificate unique ID	170773901
Effective date	2021-01-21
Expiry date	2024-05-26
Frankfurt am Main	2021-01-21

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Ortho Solutions GmbH
Eltastraße 2
78573 Wurmlingen
Germany

Our ref.: KOJ, Phone: 069 95427-542, Fax: -388
E-Mail: Judith.Koffler@dqs-med.de

Frankfurt a. M.
2022-11-28

Certification confirmation letter

To whom it may concern,

DQS Medizinprodukte GmbH is a Notified Body according to § 15 Medical Devices Act – Directive 93/42/EEC and according to Regulation (EU) 2017/745 on medical devices. After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.
We as a Notified Body will continue to perform the surveillance activities for certificates according to Directive 93/42/EEC issued by DQS Medizinprodukte GmbH, which are still valid.
DQS Medizinprodukte GmbH is registered as NB 0297.

Furthermore, DQS Medizinprodukte GmbH is an accredited certification body for management systems under the terms of DIN EN ISO/IEC 17021-1:2015 to carry out certifications of management systems according to DIN EN ISO 13485:2016.

DQS Medizinprodukte GmbH hereby confirms that the EC-Certificate (Certificate registration no. 548484 MR2 with the unique certification ID 170773901 valid from 2021-01-21 until 2024-05-26) has been issued to the following auditee:

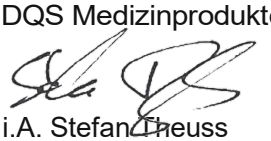
Ortho Solutions GmbH
Eltastraße 2
78573 Wurmlingen
Germany

in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC concerning medical devices.

The distribution of the following product has been stopped by the customer as of 28th November 2022 and is no longer valid on the current certificate (170773901):

Ring fixator	**Class IIb**

Yours faithfully,
DQS Medizinprodukte GmbH



i.A. Stefan Theuss
Regulatory Affairs Manager