

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7410GB445231006

Final assessment report no.
7410AU07F

Effective date
2023-10-06

Expiry date
2026-06-14

This is to certify that

SpineSave GmbH

Eichenallee 8H, 21521 Wohltorf, Germany

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2023-10-06

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany



The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Markus Bianchi
Director Certification Body



Certificate no.: [7410GB445231006](#)
Place and date: [Hamburg, 2023-10-06](#)

Sites covered by this certificate

SpineSave GmbH, Eichenallee 8H, 21521 Wohltorf, Germany
SpineSave AG, Stationsstrasse 66, 8424 Embrach, Switzerland

Activities and products/services covered by this certificate

Design and development, manufacture, final inspection and distribution of

- Spinal implant systems



EC Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company:

SpineSave GmbH
Eichenallee 8H
21521 Wohltorf
Germany

with locations listed in the appendix

has introduced, applies and maintains a quality assurance system for the products / product categories listed in the appendix.

The compliance of this quality assurance system with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex II without section 4

This certification is subject to surveillance by MEDCERT.

Effective date: 2021-05-21

Expiry date: 2024-05-27

Report No.: 7410FS04F

Process No.: QS – 7410

Certificate No.: 7410GB410210518A

Hamburg, 2021-05-18



MEDCERT Certification Body
(Lorenz Runge)

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MEDCERT Identification Number: 0482

Form F10010005e EN / Rev. 11 / 2019.11.14



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www.zlg.de
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Appendix of EC Certificate of Conformity

Process No.: QS – 7410

Certificate No.: 7410GB410210518A

List of locations included in the scope of certificate

SpineSave AG
Stationsstrasse 66
8424 Embrach
Switzerland
Germany

– End of list –

This appendix is integral part of the above-referenced certificate.
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Appendix of EC Certificate of Conformity

Process No.: QS – 7410

Certificate No.: 7410GB410210518A

List of products / product categories included in the scope of certificate

Spinal implant systems

– End of list –

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