MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final assessment report no.	Effective date	Expiry date
7410GB445231006	7410AU07F	2023-10-06	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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-19630-04-00

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

Markus Bianchi
Director Certification Body

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

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

To whom it may concern

DNV MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

Tel: +49 40 2263325-0
E-mail: Medcert-Info@dnv.com

Date: 2024-06-24

Our reference: QS-7410

Notified Body Confirmation Letter
Certification No: 7410GB454240624

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

To whom it may concern,

This letter confirms that DNV Medcert GmbH, a Notified Body (NB), designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 on Nando[1], has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer.

SpineSave GmbH
Eichenallee 8H
21521 Wohltorf
Germany
SRN[2]: DE-MF-000007418

The devices covered by the formal application and the written agreement mentioned above are identified in the tables (in the appendix of this letter). Table 1 identifies the devices for which an MDR application has been received, a written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

[1] Nando (New Approach Notified and Designated Organisations) Information System, https://ec.europa.eu/growth/tools-databases/nando/.
[2] Single registration number (SRN) according to Article 31 (2) of MDR.

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa devices, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

For DNV MEDCERT GmbH

Monika Hamann
Customer Service Manager

Appendix (see following pages):

- Table 1 and Table 2
- Revision history

Appendix

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Spinal stabilisers, dynamic type	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 7410GB410210518A 7410DE410210518A NB 0482

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None	None	None	None

Confirmation Letter Revision History:

Date	NB internal reference traceable to each version of the letter	Action
2024-06-24	7410GB454240624	Initial issue