



# EU Quality Management Certificate



This is to certify that the company

## HumanTech Spine GmbH

Gewerbestr. 5  
71144 Steinenbronn  
Germany

SRN: DE-MF-000010596

has established, implemented and maintains a Quality Management System in accordance with

### **Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	540287 MDR2017Q
Certificate ID	1000272260
Effective date	2026-02-12
Expiry date	2031-02-11
Frankfurt am Main,	2026-02-12



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zfl.de  
BS-MDR-094

## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745  
of the Council concerning medical devices with the Identification Number 0297.**  
The validity of the certification can only be verified by the QR-code.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000010596**  
**Certificate ID: 1000272260**

**Device categories and variants covered by this certificate:**

Device category: **MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**  
Product name: VENUS® Spinal Fixation System  
Risk classification: IIb implant  
Basic-UDI-DI: 42505399050MW; 42505399051MY  
42505399054N6; 42505399055N8  
42505399060MZ; 42505399061N3  
42505399070N4; 42505399071N6  
42505399405ND; 42505399406NF

Intended purpose: The implants of the VENUS® Spinal Fixation System are intended for posterior mono- or multisegmental fixation, after prior correction if necessary, and immobilization during bony fusion to achieve stabilization of the thoracic, lumbar and iliosacral spine. The VENUS® Spinal Fixation System can be used in an open or a minimally invasive surgical approach. The implants are intended for long-term stand-alone use.

Device category: **MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**  
Product name: VENUS® nano Spinal Fixation System  
Risk classification: IIb implant  
Basic-UDI-DI: 42505399080N7; 42505399081N9  
42505399082NB; 42505399085NH  
42505399090NA; 42505399091NC  
42505399096NN; 42505399097NQ  
42505399098NS; 42505399099NU  
42505399106MY; 42505399107N2

Intended purpose: The implants of the VENUS® nano Spinal Fixation System are intended for mono- or multisegmental fixation, after prior correction if necessary, and immobilization during bony fusion to achieve stabilization of the thoracic, lumbar and iliosacral spine. VENUS® nano is used in a posterior and VENUS® nano VDS in an anterior open surgical approach. Ventral derotation spondylodesis (VDS) with VENUS® nano VDS can be performed with a minimized incision size. The implants are intended for long-term stand-alone use.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: DE-MF-000010596**  
**Certificate ID: 1000272260**

**Examinations and tests performed:**

540287\_A213465MED dated 2024-02-22

540287\_A213553MED\_VENUS® Spinal Fixation System dated 2025-12-18

**Further conditions for or limitations to the validity of the certificate:**

n/a

**Reference to previous certificates:**

<b>Revision</b>	<b>Date of Issue</b>	<b>Certificate-ID</b>	<b>Description of change</b>
n/a	n/a	n/a	n/a