EU Technical Documentation Assessment Certificate

This is to certify that the company

HumanTech Spine GmbH

Gewerbestrasse 5
71144 Steinenbronn
Germany

SRN: DE-MF-000010596

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	540287 MDR2017P
Certificate ID	1000300928
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.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000010596
Certificate ID: 1000300928

Device categories and variants covered by this certificate:

Device category:	**MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**
Product nam_:	VENUS® Spinal Fixation System
Models:	n/a
Risk classification:	IIb implant
Basis-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 nam_:	VENUS®nano Spinal Fixation System
Models:	n/a
Risk classification:	IIb implant
Basis-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

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Examinations and tests performed:
540287_A213553MED dated 2025-12-18

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

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