



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.	31638920 MDR2017P
Certificate ID	1000326828
Effective date	2026-08-27
Expiry date	2031-08-26
Frankfurt am Main,	2026-08-27



DQS Medizinprodukte GmbH

Sven Hoffmann
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 Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000010596
Certificate ID: 1000326828

Device categories and variants covered by this certificate:

Device category: **MDN 1102 - Non-active osteo- and orthopaedic implants**

Product name: SAMSON® Vertebral Body Replacement System

Models: n/a

Risk classification: III

Basic-UDI-DI: 42505399018N2

42505399019N4

42505399020MM

42505399021MP

42505399022MR

42505399023MT

Intended purpose: The implants of the SAMSON® Vertebral Body Replacement System are intended to surgically reconstruct one or more vertebral bodies at the anterior thoracic and lumbar spine that have been substantially damaged or removed. Implants of the SAMSON® system are intended for long-term use with an additional dorsal fixation system (e.g. VENUS®). Devices of the SAMSON® system are not intended for stand-alone use.

When using SAMSON® implant base bodies to replace multiple vertebral bodies, or when using 12° angled endplates mounted to the base body in a caudal and/or cranial position, ventral support is recommended.

Examinations and tests performed:

540287_A213435MED_SAMSON® Vertebral Body Replacement dated 2026-07-02

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

n/a

Reference to previous certificates:

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