EU Technical Documentation Assessment Certificate

This is to certify that the company

Biedermann Motech GmbH & Co. KG

Bertha-von-Suttner-Straße 23
78054 VS-Schwenningen
Germany

SRN: DE-MF-000005455

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.

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

Devices of class IIb and III as listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	003387 MDR2017P
Certificate ID	1000127297
Effective date	2023-12-07
Expiry date	2028-12-06
Frankfurt am Main,	2023-12-07

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005455
Certificate ID: 1000127297

Device categories and variants covered by this certificate:

Device category:	**MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**
Product name:	Vertebral body prosthesis
Models:	n/a
Risk classification:	III
Basic-UDI-DI:	425086960000010069S
Intended purpose:	The vertebral body replacement and intervertebral disc replacement are used for restoring the natural lordosis, strengthening weak osseous structures and reinforcing bone cement. In addition, bony growth can be achieved by filling with bone chips or bone replacement material. The implants can be used as an intervertebral disc replacement or vertebral body replacement and support the biological process of spondylodesis.

Examinations and tests performed:
003387_A212393MED dated 2023-11-07

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
01	n/a	n/a	n/a