EU Quality Management 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, 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. Limitations to this certificate are listed in the Annex.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	003387 MDR2017Q
Certificate ID	1000154108
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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(active medical devices)

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Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005455
Certificate ID: 1000154108

Device categories covered by this certificate:

Device category:	**MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**
Risk classification:	III
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_A212423MED dated 2023-09-11

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

The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3. For placing class III medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Reference to previous certificates:

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