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 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.	003387 MDR2017Q
Certificate ID	1000252264
Effective date	2025-07-21
Expiry date	2028-12-06
Frankfurt am Main,	2025-07-21

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

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.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005455
Certificate ID: 1000252264

Device categories and variants covered by this certificate:

Produktkategorie:	MDN 1102/A - Non-active rigid osteo- and orthopaedic implants
Produktbezeichnung:	MESH/X-Cage steril / unsteril
Risikoklasse:	III
Basis-UDI-DI:	425086960000010069S
Zweckbestimmung:	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.

Produktkategorie:	MDN 1208 - Non-active non-implantable instruments
Produktbezeichnung:	Instruments for access and preparation
Risikoklasse:	Ir
Basis-UDI-DI:	425086960000010029J
Zweckbestimmung:	Group 2: The instruments are used for preparation of the surgical area and to prepare the vertebral body, in order to be able to insert the implant system. This includes, among other things, the clearing of the spinal disc space and the drilling and tapping into the vertebral bodies.

Produktkategorie:	MDN 1208 - Non-active non-implantable instruments
Produktbezeichnung:	Instruments for insertion, positioning, and fixing
Risikoklasse:	Ir
Basis-UDI-DI:	425086960000010029J
Zweckbestimmung:	Group 3: The instruments are used for implantation through insertion, positioning and fixing of the implants. With the help of the instrument set, the implants are inserted into the body, positioned within, and fixed at the end. The instruments include screwdrivers, head inserters, etc.

Examinations and tests performed:
003387_A212393MED_01 dated 2023-09-11
003387_A215753MED_02 „GH-0200 Instruments Ir" dated 2025-07-14

Further conditions for or limitations to the validity of the certificate:
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

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Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-12-07	1000154108	Addition „GH-0200 Instruments Ir"