

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 808965 R000

**Manufacturer:** Tecomet Inc.

**Address:**

5307 95th Avenue  
Kenosha  
Wisconsin  
53144  
USA

**Single Registration Number:** US-MF-000027544

**EU Authorised Representative:** Meditec Source GmbH & Co. KG

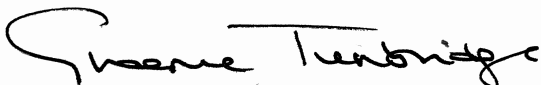
**Address:**

Sattlerstr. 19  
78532 Tuttlingen  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-05-14**

Current Issue Date: **2025-05-14**

Starting Validity Date: **2025-05-14**

Expiry Date: **2030-05-13**

...making excellence a habit.™

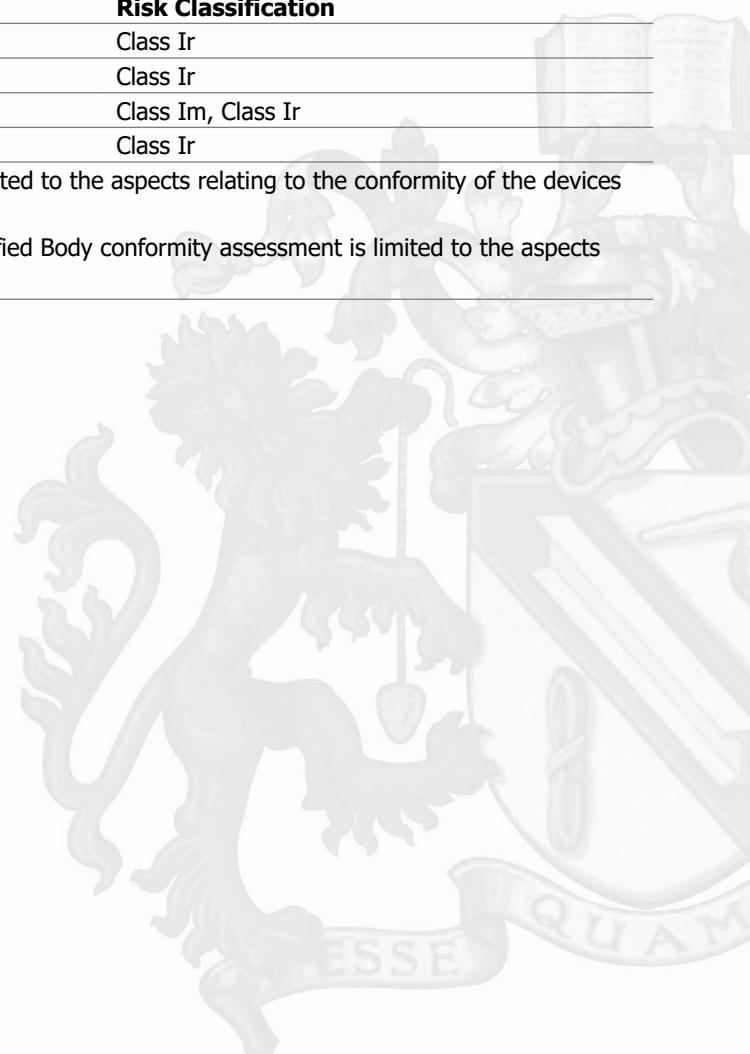
# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 808965 R000

### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sharp Instruments, Reusable	Class Ir
Orthopaedic and Traumatological Surgery Instruments, Reusable	Class Ir
Orthopaedic and Traumatological Surgery Instruments, Reusable	Class Im, Class Ir
Surgical Screwdrivers, Reusable	Class Ir
For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	



First Issue Date: **2025-05-14**

Current Issue Date: **2025-05-14**

Starting Validity Date: **2025-05-14**

Expiry Date: **2030-05-13**

...making excellence a habit.™

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

**MDR 808965 R000**

## Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))*

Date	Reference Number	Action
Current	30167123	Issued



First Issue Date: **2025-05-14**

Current Issue Date: **2025-05-14**

Starting Validity Date: **2025-05-14**

Expiry Date: **2030-05-13**

...making excellence a habit.™