



*Certificate of Registration*

*This is to certify that the Quality Management System for Medical Devices of*

**Craniotech (Pty) Ltd.  
Stellenbosch**

*Has been assessed and found  
to satisfy the requirements of*

**ISO 13485:2016  
QUALITY MANAGEMENT SYSTEMS  
FOR MEDICAL DEVICES**

*in respect of*

***Manufacturing and supply patient-specific moulds for implantable  
medical devices and patient-specific implants.***

**NON-APPLICABLE CLAUSES:**

Clause 7.5.3 Installation Activities

Clause 7.5.4 Servicing Activities

Clause 7.5.5 Particular requirements for sterile medical devices

Clause 7.5.7 Particular requirements for validation of processes for sterilization and  
sterile barrier system

**This certificate, including the schedule which forms an integral part thereof:**

- Is issued without alteration;
- Is identified by the applicable registration number;
- Is subjected to any condition or limitation contained therein;
- Is valid subject to ongoing compliance with certification requirements;
- Bears the embossed SACAS seal. In absence of the seal, the certificate and the schedule shall be invalid.
- The certificate stays the property of SACAS.
- SACAS web-site to be verified ensuring certificate is valid. ([www.sacas.co.za](http://www.sacas.co.za))

Registration Number **QMSMED00011**

Effective Date **16 July 2021**

Expiry Date **15 July 2024**

Date of Original Registration **16 July 2021**

Managing Director



C 59h

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