



## *Certificate of Registration*

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

**ORMCO South Africa (Pty) Ltd.**

**Unit 13, 38 Elandstreet, Quagga Industrial Park,  
Quaggafontein, Bloemfontein**

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

**ISO 13485:2016**

**QUALITY MANAGEMENT SYSTEMS  
FOR MEDICAL DEVICES**

*in respect of*

***Distributor of Orthodontic and dental supplies  
for the South African and African market.***

**EXCLUDING/NON-APPLICABLE CLAUSES:**

- Clause 7.3 Design and development
- Clause 7.5.2 Cleanliness of product
- 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 systems

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

**QMSMED00051**

Effective Date

**27 November 2024**

Expiry Date

**26 November 2027**

Date of Original Registration

**27 November 2024**

Managing Director



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