

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2118417-1

Organization: OSA Technology Sdn Bhd
Block C, UKM-MTDC
Smart Technology Centre II
Universiti Kebangsaan Malaysia
43600 Bangi, Selangor D.E.
Malaysia

Scope:

- Design and Development, Manufacture and Distribution of Non-sterile Orthopaedic Trauma Fixation Implants
- Design and Development, Manufacture and Distribution of Optical Non-Intrusive Blood Glucose Detector
- Manufacture and Distribution of Non-sterile face mask, Isolation gowns, Coveralls, Capes, Coats, Aprons, Headwear and footwear for Medical and Protective Equipment Purposes
- Contract manufacture of Dental implant and Blood glucose measuring strip
- Manufacture and Distribution of Wound Dressings, Surgical Drapes, Surgical Tapes and Sterile Instrument Covers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 250110083-22

Effective date: 2022-02-01

Expiry date: 2024-08-03

Issue date: 2022-02-01



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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o OSA Technology Sdn Bhd Block C, UKM-MTDC Smart Technology Centre II Universiti Kebangsaan Malaysia 43600 Bangi, Selangor D.E. Malaysia	-Design and Development, Manufacture and Distribution of Non-sterile Orthopaedic Trauma Fixation Implants -Design and Development, Manufacture and Distribution of Optical Non-Intrusive Blood Glucose Detector -Contract manufacture of Dental implant and Blood glucose measuring strip
/02	c/o OSA Technology Sdn Bhd Block Intron Ekson B3-11 UKM-MTDC Smart Technology Centre II Universiti Kebangsaan Malaysia 43600 Bangi, Selangor Malaysia	-Manufacture and Distribution of Non-sterile face mask, Isolation gowns, Coveralls, Capes, Coats, Aprons, Headwear and footwear for Medical and Protective Equipment Purposes -Manufacture and Distribution of Wound Dressings, Surgical Drapes, Surgical Tapes and Sterile Instrument Covers

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