



INTERNATIONAL  
ACCREDITATION  
SERVICE®

# CERTIFICATE OF ACCREDITATION

*This is to attest that*

## **ZENITH QUALITY ASSESSORS PRIVATE LIMITED**

OFFICE NO. 01A, B-WING, SIDDHESH OPTIMUS, S. NO. 211  
VIMAN NAGAR, PUNE, MAHARASHTRA 411014  
REPUBLIC OF INDIA

### **Management System Certification Body MSCB-128**

has met the requirements of AC477, *IAS Accreditation Criteria for Management System Certification Bodies*, and has demonstrated compliance with the ISO/IEC 17021-1:2015 Standard, *Conformity assessment – Requirements for bodies providing audit and certification of management systems*. This organization is accredited to provide the services specified in the scope of accreditation.

*Effective Date November 19, 2024*

(Valid as per IAS 4-year accreditation cycle subject to periodic assessments and satisfactory closure of findings)

Accredited Since January 5, 2017



**President**

Visit [www.iasonline.org](http://www.iasonline.org) for current accreditation information.

# SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | [www.iasonline.org](http://www.iasonline.org)

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[www.zenith-worldwide.com](http://www.zenith-worldwide.com)

**MSCB-128**

**Contact Name** Mr. Pradyut Bera

**Contact Phone** +91-9607006692 /

9607006823 / 9607006973 /

9607006945 / 9607004749

Accredited to ISO/IEC 17021-1:2015

*Effective Date November 19, 2024*

|  |  |
|--|--|
| <b>Discipline of Certification:</b>  | Quality Management Systems   |
| <b>Accredited To/Additional Level 4 Standard:</b>  | ISO/IEC 17021-3:2017   |
| <b>Certification Standard:</b>   | ISO 9001:2015  |
| <b>Certification Scheme:</b>   | N/A  |
| <b>Certification Sectors</b>   |  |
| 3: Food Products, Beverages and Tobacco<br>4: Textiles and Textile Products<br>13: Pharmaceuticals<br>14: Rubber and Plastic Products<br>17: Basic Metals and Fabricated Metal Products<br>18: Machinery and Equipment<br>19: Electrical and Optical Equipment | 22: Other Transport Equipment<br>23: Manufacturing Not Elsewhere Classified<br>28: Construction<br>32: Financial Intermediation, Real Estate, Renting<br>33: Information Technology<br>39: Other Social Services |

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|   |  |
|---|--|
| <b>Discipline of Certification:</b>                                 | <i>Medical Device Quality Management Systems</i>   |
| <b>Accredited To/Additional Level 4 Standard:</b>                   | <i>No additional level 4 standard</i>  |
| <b>Certification Standard:</b>                                      | <i>ISO 13485:2016</i>  |
| <b>Certification Scheme:</b>  | <i>N/A</i>   |
| <b>Certification Sectors</b>  |  |
| A: Non-Active Medical Devices                                       | General Non-Active, Non-Implantable Medical Devices<br>Non-Active Implants<br>Devices for Wound Care<br>Non-Active Dental Devices and Accessories<br>Non-Active Medical Devices Other than Specified Above   |
| B: Active Medical Devices (Non-Implantable)                         | General Active Medical Devices<br>Devices for Imaging<br>Monitoring Devices<br>Devices for Radiation Therapy and Thermo Therapy<br>Active (Non-Implantable) Medical Devices Other than Specified Above   |
| C: In Vitro Diagnostic Medical Devices (IVD)                        | Reagents and Reagent Products, Calibrators and Control materials for:<br>-Clinical Chemistry<br>-Immunochemistry (Immunology)<br>-Haematology/Haemostasis/Immunohematology<br>-Microbiology<br>-Infectious Immunology<br>-Histology/Cytology<br>-Genetic Testing<br>In Vitro Diagnostic Instruments and Software<br>IVD Medical Devices Other than Specified Above |
| D: Sterilization Methods for Medical Devices                        | Ethylene oxide gas sterilization (EOG)<br>Moist heat<br>Aseptic processing<br>Radiation sterilization (e.g., gamma, x-ray, electron beam)<br>Low temperature steam and formaldehyde sterilization<br>Thermic sterilization with dry heat<br>Sterilization with hydrogen peroxide<br>Sterilization method other than specified above                                |
| E: Devices Incorporating/Utilizing Specific Substances/Technologies | Medical Devices Incorporating Medicinal Substances<br>Medical Devices Utilizing Tissues of Animal Origin<br>Medical Devices Utilizing Nanomaterials<br>Medical Devices Utilizing Biological Active Coatings and/or Materials or Being Wholly or Mainly Absorbed  |
| F: Parts or Services  | Raw Materials<br>Components<br>Subassemblies<br>Calibration Services<br>Distribution Services<br>Maintenance Services<br>Transportation Services<br>Other Services   |

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|   |   |
|---|---|
| <b>Discipline of Certification:</b>   | <i>Food Safety Management Systems</i>                                       |
| <b>Accredited To/Additional Level 4 Standard:</b>   | <i>ISO 22003-1:2022</i>   |
| <b>Certification Standard:</b>  | <i>ISO 22000:2018</i>   |
| <b>Certification Scheme:</b>  | <i>N/A</i>  |
| <b>Food Safety Categories</b>   |   |
| <i>C: Food, ingredient and pet food processing<br/>E: Catering/food service<br/>F: Trading, retail and e-commerce</i> | <i>I: Production of packaging material<br/>K: Chemical and bio-chemical</i> |

|  |  |
|--|--|
| <b>Discipline of Certification:</b>  | <i>Food Safety System Certification</i>  |
| <b>Accredited To/Additional Level 4 Standard:</b>  | <i>ISO 22003-1:2022<br/>Additional Requirements as specified in the FSSC 22000 Scheme<br/>ISO/TS 22002-1:2009<br/>ISO/TS 22002-2:2013<br/>BSI/PAS 221:2013<br/>ISO/TS 22002-4:2013<br/>ISO/TS 22002-1:2009</i> |
| <b>Certification Standard:</b>   | <i>FSSC 22000 V. 6.0</i>   |
| <b>Certification Scheme:</b>   | <i>N/A</i>   |
| <b>Food Safety Categories (Subcategories)</b>  |  |
| <i>C: Food, ingredient and pet food processing (CI, CII, CIII, CIV)<br/>E: Catering/food service<br/>F: Trading, retail and e-commerce (FI, FII)</i> | <i>I: Production of packaging material<br/>K: Chemical and bio-chemical</i>  |

*Note: The above scope of accreditation is based on the statistical nomenclature for economic activities NACE rev. 2 and as recommended by the current version of IAF ID 1.*

The scope of accreditation represents broad classifications granted by IAS on the basis of the management system certification processes demonstrated by the certification body (CB). Accreditation is based on the competence and ability to effectively apply the requirements of the relevant certification standards listed in the CB's scope of accreditation. IAS accreditation entails review of the CB's own management system, on-site assessment of the CB's certification processes, review of CB's access to expertise including onsite observation of the CB when conducting certification audits at client sites. Under the conditions of accreditation, the CB is obligated to use equivalent certification practices covering the specific scopes as listed for all clients and as demonstrated during the accreditation process. Accreditation does not cover certification in areas outside the scope of this accreditation certificate. Accreditation does not imply endorsement of the products or the design or performance characteristics of products certified by the CB.

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| Type of entity                       | Company name | Address (Street City, Country) | Contact information |
|--------------------------------------|--------------|--------------------------------|---------------------|
| Key Locations                        | N/A          | N/A                            | N/A                 |
| Subcontractor<br>(No Key Activities) | N/A          | N/A                            | N/A                 |

The above table lists any entities performing work on behalf of the accredited MSCB (See IAF MD23:2018, IAF/ILAC A5:11/2013 and IAS/MSCB/031 for information regarding types of activities per entity). Types of entities and their descriptions are as follows (please contact IAS should further clarification be required):

**CB Key Location:** Entities performing and/or managing key management system certification activities, on behalf of accredited certification bodies, which are wholly or partly owned or employed by the CB.

**Subcontractor Key Location:** Entities performing and/or managing key management system certification activities, on behalf of accredited certification bodies, which are not wholly or partly owned or employed by the CB.

**Subcontractor (No Key Activities):** Entities performing and/or managing processes related to management system activities, on behalf of accredited certification bodies, which are not wholly or partly owned or employed by the CB (processes include; marketing, communications, outreach, etc.) This list is not all-inclusive; any activity related to the accredited CBs certification program is applicable.