## SCOPE OF ACCREDITATION

<table>
<thead>
<tr>
<th><strong>IAS Accreditation Number</strong></th>
<th>MSCB-126</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company Name</strong></td>
<td>UL Registrar LLC</td>
</tr>
<tr>
<td><strong>Address</strong></td>
<td>4 Fork Street, Mount Pocono, PA 18344 USA</td>
</tr>
<tr>
<td><strong>Contact Name</strong></td>
<td>Bryce Carson, General Manager</td>
</tr>
<tr>
<td><strong>Telephone</strong></td>
<td>+1 (800) 903-5660</td>
</tr>
<tr>
<td><strong>Key Locations</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Effective Date of Scope</strong></td>
<td>July 13, 2017</td>
</tr>
<tr>
<td><strong>Accreditation Standard</strong></td>
<td>ISO/IEC 17021-1</td>
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### Discipline of Certification:
- Medical Device Quality Management Systems

### Certification Standard:
- ISO 13485:2016

### Certification Scheme:
- N/A

### Certification Sectors

**A: Non-Active Medical Device Technical Area**

- General Non-Active, Non-Implantable Medical Devices
- Non-Active Implants
- Devices for Wound Care
- Non-Active Dental Devices and Accessories

**Non-Active Medical Devices Other than Specified Above:**
- Non-active devices for anesthesia, emergency and intensive care
- Non-active devices for injection, infusion, transfusion and dialysis
- Non-active orthopedic and rehabilitation devices
- Non-active medical devices with measuring function
- Non-active ophthalmologic devices
- Non-active instruments
- Contraceptive medical devices
- Non-active medical devices for disinfecting, cleaning, rinsing
- Non-active devices for in vitro fertilization (IVF) and assisted reproductive technologies (ART)
- Non-active medical devices for ingestion
- Non-active cardiovascular implants
- Non-active orthopedic implants
- Non-active functional implants
- Non-active soft tissue implants
- Bandages and wound dressings
- Suture material and clamps
- Other medical devices for wound care
- Non-active dental devices/equipment and instruments
- Dental materials
- Dental implants
### SCOPE OF ACCREDITATION

<table>
<thead>
<tr>
<th>D: Sterilization Methods for Medical Devices</th>
<th>Ethylene Oxide Gas Sterilization (EOG)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Moist Heat</td>
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<tr>
<td></td>
<td>Aseptic Processing</td>
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<tr>
<td></td>
<td>Radiation Sterilization (e.g. Gamma, X-Ray, Electron Beam)</td>
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<tr>
<td></td>
<td>Sterilization Method Other than Specified Above</td>
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</tbody>
</table>

**Note:** The above scope of accreditation is based on the statistical nomenclature for economic activities NACE rev. 2 and recommended by IAF ID 1:2014.

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 CBs 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.