**Initial Approval Requirement**

**Medical Devices Authorized Representative Registration Check List**

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| **Authorized Representative Name**:  |  **Date:** |
| **Applicant Name**: | **Contact No** |
| **Email:** |  |

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| * **Documents Required**
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| 1. Medical Device Company Registration form. (All sections need to be filled).
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| 1. Valid Commercial Registration (CR). / For new companies, you can write the CR application number on Sijillat.
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| 1. Company Policies:
2. Services maintenance b) Complaint handling

c) Adverse events d) Recalls e) Distribution |
| 1. Authorization Letters or Agreements and should be valid, signed and stamped by the manufacturers. For new companies, please refer to the requirement in section 7.
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| 1. Capture one page of company system (Software or Excel Sheet) to monitor and trace the distribution of medical devices, maintenance, recall and adverse events.
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| 1. List of company’s staff and CVs, qualifications, training courses certificates if any.
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| 1. List of products with a clear scope of service and official list of products (ex: dental, ortho, surgical, lab, ENT…) the certificate will be issued for the scope selected only.
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