

## Manufacturers Certified to ISO 13485:2016

### Required documents

### Provided

- 1 Business registration certificate
- 2 Manufacturing license
- ISO 13485: 2016 certificate (including scope of certification, cert number,
- 3 expiry date and issuing certification body)
- 4 Write up/regulatory evidence of Class I global regulatory approvals (across devices)
- 5 CE Certificate for currently marketed devices

## Manufacturers working towards ISO 13485 Certification

### Required documents

### Provided

- 1 Business registration certificate
- 2 Manufacturing license
  
- 3 Formal ISO 13485 Implementation plan with targeted certification date
- 4 Gap Analysis summary (if available)
- 5 Engagement letter with Certification body (if initiated)
- 6 Draft of the implemented Quality Manual
- 7 Management commitment evidence