# Audit Plan <Date>

## 1. General Information

|  |  |
| --- | --- |
| Audit Program | <reference record here> |
| Year |  |
| Audit Number |  |

|  |  |
| --- | --- |
| Auditor Team | <name auditor participants here> |
| Audit Type | <e.g. internal (first-party) audit> |
| Audit Scope | Pursuant to audit plan, para. 4 |
| Audit Date |  |
| Audit Time | <e.g. 09.00 - 17.00> |

## 2. Audit Participants

| Name | Position / Role |
| --- | --- |
| Albert Dreary | CEO |
| Frodo Baggins | QMO |
| Samwise Gamgee | Assistant Director |
| (…) | (…) |

## 3. Audit Criteria

| No. | Audit Criterion |
| --- | --- |
| 1 | EN ISO 13485:2016 (ed3) |
| 2 | (EU) Medical Device Regulation 2017/745 |

## 4. Audit Activities

### Day 1

| Time | Topic / Operational Unit / QMS Process | Audit Criteria | Participants |
| --- | --- | --- | --- |
| 08.00 - 08.15 | Introduction | n/a | Dreary (CEO), Baggins (QMO) |
| 08.15 - 09.15 | QMS General Information,<br>Documentation Requirements | EN ISO 13485:2016, para. 4.1 and 4.2 | Dreary (CEO), Baggins (QMO) |
| 09.15 - 10.00 | Management Responsibility | EN ISO 13485:2016, para. 5.1 - 5.3, 5.5, 5.6 | Dreary (CEO), Baggins (QMO) |
| 10.00 - 10.45 | Resource Management | EN ISO 13485:2016, para. 6.1 - 6.3 | Dreary (CEO), Baggins (QMO) |
| 10.45 - 11.00 | Break |  |  |
| 11.00 - 11.45 | Product Realization | EN ISO 13485:2016, para. 7.1 | Baggins (QMO), Gamgee (As. Director) |
| 11.45 - 12.00 | Summary |  |  |

### Day 2

| Time | Topic / Operational Unit / QMS Process | Audit Criteria | Participants |
| --- | --- | --- | --- |
| (…) | (…) | (…) | (…) |
|  |  |  |  |

## 5. Release

|  |  |
| --- | --- |
| Auditor Name |  |
| Release Date |  |
| Auditor Signature |  |

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