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, Documentation Requirements	EN ISO 13485:2016, para. 4.1 and 4.2	Dreary (CEO), Baggins (QMO)

Time	Topic / Operational Unit / QMS Process	Audit Criteria	Participants
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