Agenda:

Process Activities	Auditor	Auditor	Time planning
Day 1: June 7, 2021			
Opening meeting, introduction, finalize agenda	#1	#2	09:00
Certification update/Management System Dynamics • Changes in the organization; • Changes to quality management system documents; • Changes to subcontractors, certification status; • Changes to products, additions/deletions to products offered; • Use of Certification Marks and other references to certification • Updates to CN (including latest DoC's) • Status of the audit matrix; • Future projects/products/changes;	#1		09:30
Management Processes (Tasks 1 - 6)		#2	09:30
Management Processes (Tasks 7 - 8)	#1		10:30
Lunch			12:00
Management Processes (Tasks 9 & 11)		#2	12:30
Management Processes (Task 10 -11)	#1		12:30
Device Marketing Authorization and Facility Registration (Task 1-3)	#1		13:45
Measurement, Analysis and Improvement (Task 1-7) • CAPA		#2	13:45
Measurement, Analysis and Improvement (Task 10) • Internal Audit	#1		15:45
Auditor Caucus	#1	#2	17:00
Wrap-up meeting audit day	#1	#2	17:15
End of audit day	#1	#2	17:30
Day 2: June 8, 2021			
Measurement, Analysis and Improvement (Task 8-9, 11, 16) • Nonconforming Product		#2	9:00
Measurement, Analysis and Improvement (Task 12 - 16) • Post Market Surveillance and Complaint Handling	#1		9:00
Medical Device Adverse Events and Advisory Notice Reporting (Task 1 - 2)	#1		11:00

Process Activities	Auditor	Auditor	Time planning
Design and Development (Task 1-11, 13-17)		#2	11:00
Lunch			12:00
Purchasing (Task 1-12)	#1		12:30
Design and Development (Task 1-11, 13-17) - Continued		#2	12:30
Production and Service Controls (Task 4-6) • Control of product cleanliness • Infrastructure • Work environment	#1		15:00
Production and Service Controls (Task 1-3)		#2	15:30
Auditor Caucus	#1	#2	17:00
Wrap-up meeting audit day	#1	#2	17:15
End of audit day	#1	#2	17:30
Day 3: June 9, 2021			
Production and Service Controls (Tasks 10-11, 19-20, 22-25, 28, 29) • Manufacturing Process • Process control and monitoring • Nonconforming product • Customer property • Preservation of product • Customer requirements and distribution records	#1		09:00
Production and Service Controls (Tasks 7-8, 12-14, 15-17, 21, 29) • Training and competency • Calibration • Process validation • Device master file • Production records • Identification and traceability		#2	9:00
Lunch			12:00
Auditors prepare for closing meeting	#1	#2	12:30
Closing meeting	#1	#2	13:00
End of onsite audit	#1	#2	13:30