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Product Service

Audit Plan

Version __0__
Order no.: ITA 1691847

1 Audit Overview

Type of Audit	☐Stage 1 ☐Stage 2 ☐Stage 1 + Stage 2 ☐Re-Certification ☐1st Surveillance ☐2nd Surveillance ☐Surveillance 1 Remote A ☐Surveillance 2 Remote A ☒Recertification Remote A ☐Surveillance 1 Remote A2 ☐Surveillance 2 Remote A2 ☐Recertification Remote A2 ☐Surveillance 1 Follow-up B ☐Surveillance 2 Follow-up B ☐Recertification Follow-up B ☐Early Recertification (Post-Part A) ☐Special Audit Type: _____
Additional Type of Audit	☐Scope Expansion QMS (Products / Processes / Facilities) ☐Scope Expansion Regulatory (Products / Processes / Facilities) ☐Upgrade / change QMS Standard ☐Other: _____
Audit criteria	☒ (DIN) EN ISO 13485:2016 ☒ ISO 13485:2016 ☐ Taiwan GMP ☐ (DIN) EN ISO 9001:2015 ☒ ISO 9001:2015 ☐ Other: _____ ☐ Defined processes and documentation of the auditee's Quality Management System • European Directives: ☒ Council Directives 93/42/EEC (MDD) – annex II (w/o 4) ☒ Council Directives 93/42/EEC (MDD) – annex V ☒ Council Directives 93/42/EEC (MDD) – annex VI ☐ Council Directives 90/385/EEC (AIMDD) – annex 2 (w/o 4) ☐ Council Directives 98/79/EC (IVDD) – annex IV ☐ Council Directives 98/79/EC (IVDD).– annex VII
Audit period (on site)	28/04/2021 - 29/04/2021
Auditee (s) / Location(s)	FAZZINI S.r.l., SS Padana Sup. 317, 20090 Vimodrone (MI), Italy (44963)
Audit Responsible	Daniele Dipinto
Lead Auditor / Auditor	Roberto Gabriotti (RG)/
Expert / Trainee	None

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Auditor Reg. No. (Mainland China only)	None
Translator / Observer and their organization	None
QM Manual: Revision / Date	Current version
Audit Language	Italian
First release of Audit Plan / Date	2021-04-01

1.1 Audit Objectives

The objectives of this Audit are:
- Determine conformance of the Management System with the Audit Criteria (see above)
- Evaluate the effectiveness of the Management System in meeting its specified quality objectives
- Evaluate the capability of the Management System to ensure compliance with relevant statutory, regulatory and contractual requirements (as applicable)
- Evaluate the effectiveness of the Management System to ensure that agreed requirements for products and/or services are met
- Identify areas for potential improvement of the Management System
- Evaluate the effectiveness of the corrective actions related to the Nonconformities and Minor Nonconformities of the previous Audit (if applicable)
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2 Audit Program(s)

- The completion of the audit program(s) and the fulfilment of code requirements shall be in accordance with MED W 09.16, including the limitations for use of QMS auditors.
- If the audit is related to MED W 09.46, then the clause coverage related to the combination of the Part A and Part B audit should be entered into the audit being replaced by the MED W 09.46 approach.
- A separate audit program should be completed for all audits within the three-year cycle for each site and scheme included in the audit. If a scheme is not applicable, then the associated audit program can be deleted.
- For (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation and the ISO 9001:2015 Audit Programs:
    - Recertification/Initial Audit after 6/20/2020: If an "X" is in the "Every S", then clause must be audited every surveillance and if an "M" is in "Every S", then the clause must be audited every surveillance in a joint audit with MDSAP.
    - Recertification/Initial Audit prior to 6/20/2020: The existing audit program can be followed by transposing the details to the tables below. For convenience, clauses that were required in the prior versions of the audit plan are marked with grey columns.

2.1 (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation

Planning according to (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation per Location: 1

Clauses	4	5	6					7																						
			1	2	3	4		1	2				3									4			5					
						1	2		1	2	3	1	2	3	4	5	6	7	8	9	10	1	2	3	1	2	3	4	5	6	7	8
Cert / Recert	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Every S	X	X		M				X		M	M									M		M			M							
S1	X	X	X	X		X	X	X														X	X	X	X	X	X	X	X	X	X	X
S2	X	X	X		X			X	X	X	X	X	X	X	X	X	X	X	X	X	X				X							X

Clauses	7				8															
	5			6	1	2					3				4	5		
	9	10	11			1	2	3	4	5	6	1	2	3	4		1	2	3
Cert / Recert	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Every S	M					X	X	M	X	X	X			M		X	X	X	X
S1	X	X	X		X	X	X	X	X	X	X						X	X	X
S2	X			X		X	X	X		X	X	X	X	X	X	X	X	X	X

Cycle	EA Code(s)	MD/ IVD Code(s)	MDS Code(s)
Cert / Recert	19, 29a (Technical Areas – applicable only for TUV Italia: 1.1.A, 1.2.A e 1.2.C)	MD / IVD-code(s): MD 0101_2_3 (OEM), MD1302 (OEM); MD 1102, MD 1104_1; EA 19, 29a (Technical Areas – applicable only for TUV Italia: 1.1.A, 1.2.A e 1.2.C)	NA
S1	19, 29a (Technical Areas – applicable only for TUV Italia: 1.2.A e 1.2.C)	MD / IVD-code(s): MD1302 (OEM); MD 1102, MD 1104_1, MD 1301 (class Im)	NA
S2	29a (Technical Areas – applicable only for TUV Italia: 1.1.A,)	MD / IVD-code(s): MD 0101_2_3 (OEM), MD 0104 (OEM, class Im)	NA
If multiple site, note site specific differences for codes or process:			

Cycle	MDT/IVT Code(s)	MDS/IVS Code(s)	MDA/MDN/IVR Code(s)	IVP/IVD Code(s)
Cert / Recert	NA	NA	NA	NA
S1	NA	NA	NA	NA
S2	NA	NA	NA	NA
If multiple site, note site specific differences for codes or process:				

* „M" signifies that the clause must be audited every surveillance when the audit is a joint audit with MDSAP

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3 Audit Plan

- Within the Audit Scope, include the applicable ISO clauses, process name, task name (MDSAP only), and task number (MDSAP only). If regulations or directives are applicable, then explicitly document their coverage in the plan.
- If more than one site is being audited, it shall be clearly documented which site is being addressed in each element listed in the audit plan.
- If the audit is conducted remotely and/or utilizes ICT technology, then the specific tools used (e.g. WebEx, Adobe Connect, e-mail, teleconference) within each process must be detailed.

Date / Time **Auditor, Expert, Trainee**	**Function / Unit / Location**	**Audit Scope (Process)**	**Participants Auditees**
2021-04-28	**FAZZINI Headquarter - REMOTE**		
09:00-09:30 RG	Direction, Quality Virtual Room A	**Opening meeting** QS scope confirmation Changes from last audit Overview on main processes and critical supplier	Direction QS manager
9.30-10.30 RG	Direction QS dept. Virtual Room A	Direction Processes (#5, #6.1, # 8.1, #8.2.5, #8.5.1) Including specific requirements ISO 9001:2015 (risk and opportunities, interested parts and context analisys)	CEO QS manager
10.30-11.30 RG	QS dept. Virtual Room A	Quality Management system (#4), use of the logo certification, QS change, validation of software used in QMS	QS manager
11.00-13.00 RG	QS dept. Virtual Room A	QS monitoring process: customer complaints and PMS (#8.2.1, #8.2.2), internal audits (#8.2.4), Vigilance/recall (#8.2.3, 8.3.3), NC (#8.3.1, #8.3.2) and CAPAs (#8.5.2, #8.5.3)	QS manager
13:00-14:00		Lunch Break	
14.00-15.00 RG	Direction, Quality Virtual Room A	Review findings from previous audit	Direction QS manager
15.00-17.00 RG	R&D dept. Virtual Room A	R&D process (#7.3) including design transfer and changes *[active medical devices: MD1302 (OEM); MD 1102, MD 1104_1, MD 1301 (class Im)]*	R&D manager, staff
17.00-18.00 RG	QS dept. Virtual Room A	EC Directive requirements	QS manager
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09.00-10.00 RG	Commercial dept. Virtual Room A	Commercial dept. including customer satisfaction and distribution process (#7.2)	Commercial manager, staff
10.00-11.00 RC	HR dept. Virtual Room A	Human resources (#6.2)	HR manager, staff
11:00.-12.00 RC	Purchasing dept. Virtual Room A	Purchasing dept. (#7.4) including control of OEM suppliers	Purchasing manager, staff
12.00-12.30 RC	QS dept. Virtual Room A	Control of outsourcing (#4.1.5)	QS manager
12.30-13.00 RG		Auditor's preparation	
13:00-14:00		Lunch Break	
14.00-14.55 RG	Direction, QS dept. Virtual Room A	Closure meeting	CEO QS manager
14.55	Direction, QS dept. Virtual Room A	END OF THE AUDIT	CEO QS manager

A room for the Audit Team should be provided to ensure undisturbed communication as well as safe keeping of documents. The Auditors are accompanied by the Audit responsible during the Audit. The Audit Plan can be adjusted during the Audit.
Opening and closing meeting are fixed.

Please note: The company and the Lead Auditor should discuss any personal protective equipment needed for the Audit well in advance before the start of the Audit. Protective equipment (helmet, safety shoes, safety goggles, cleanroom clothes) must be provided by the audited company.

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4 Signatures

The parties agree that the contract shall be concluded in text form. To comply with this requirement any transmission using telecommunication means (e.g. via letter, fax, e-mail) and a simple signature (e.g. by electronic signature with Adobe Sign) is sufficient.

The complete audit plan record may consist of two documents: (1) The audit plan signed by the audit team and client prior to the audit, Sections 4.1 and 4.2; (2) The audit plan signed by the lead auditor after the audit, Section 4.3.

4.1 Audit Team (Prior to the Opening Meeting)

- We have read, understood and accepted the "Independence, Impartiality, Conflict of Interest and Confidentiality Requirements" procedure MED_P_09.09.
- To the best of our knowledge we hereby declare that we are independent, impartial and objective in respect of this project and have no conflict of interest.
- Lead Auditor: I confirm that the Audit Plan is released prior to the Audit.

Auditor(s) / Expert(s) / Trainee (signature, date)

		Roberto GABRIOTTI
	C. GHERARDI	2021-04-28

4.2 Client (Prior to the Opening Meeting)

- We confirm that Quality Management System certification marks are not used in any advertising that implies that they apply to products.
- We confirm that this Audit Plan including Audit objectives are accepted.
- We confirm that the Auditors / Experts / Translator are accepted.
  - Including the fact that the following person(s) is/are employed by the local TÜV SÜD Product Service company: None
  - Including the fact that the following person(s) is/are not employed within the TÜV SÜD Group: Roberto Gabriotti
- We confirm that we have the necessary infrastructure to support the Information and Communication Technology (ICT) proposed within the audit program and approve the use of ICT.

Audit Responsible (signature, date)

2021-04-28

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4.3 Lead Auditor (Prior to Closing Meeting)

The audit has been performed as documented within this audit plan.

Based on the objective evidence, the Audit Team confirms that the Audit objectives have been met. The Audit Team concludes that the company's Quality Management System

☒ Conforms with the Audit criteria as specified above

☐ Does not fully conform with the Audit criteria as specified above.
The Audit Team did identify nonconformities
Refer to See **Findings List** for more details including follow-up actions

☐ Re-Certification Audit:
The Audit results from the last three (3) years were considered for both the Audit planning and the current conclusion for this recertification

Lead Auditor (signature, date):

2021-04-29

cc: Audit responsible; Audit Team members, Certification Body

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5 Version History

Rev. No.	Date (yyyy-mm-dd)	Name	Description of Change
0	2021-04-01	Riccardo Cottone	Creation of report
1			