Audit Plan

Revision 8 (April 2020)

Date	Time	Auditor/ Auditee	Process (Skype)	Clause
13 Oct 2020	08:45	A Di Noia /	ICT Test and Connection	-
	09:00	A Di Noia / Derek Lamb	Opening Meeting and Updates	-
	09:20	A Di Noia / Derek Lamb	Scope/product changes, manual, policy, confirm essential audit information	4.2, 5.3
	09:45	A Di Noia / Derek Lamb	Management review, objectives, targets, data analysis	5.4, 5.6, 8.4
	10:15	A Di Noia / Derek Lamb	Internal Audit process and follow ups	8.2.4
	11:00	A Di Noia / Derek Lamb	Corrective & preventive action processes including review of previous BSI NC report 9636270	8.5.2, 8.5.3
	12:30	All	Lunch Break	-
	13:00	A Di Noia / Derek Lamb	Feedback Processes, Complaint Management, Vigilance and advisory notices Communication to legal manufacturers	8.2.1, 8.2.2, 8.2.3, 8.3.3
	13:45	A Di Noia / Derek Lamb	Customer related processes Servicing activities, warehouse/picking/distribution/despatch with linkage to work environment / infrastructure & maintenance processes and trainings	7.2, 7.5, 6.3, 6.4, 6.2
	15:30	A Di Noia / Derek Lamb	Supply chain: purchasing, outsourcing, supplier controls, goods-in, warehouse controls, traceability.	7.4, 7.5.8, 7.5.9, 7.5.10
	16:15	A Di Noia / Derek Lamb	Control of nonconforming product	8.3
	16:45	A Di Noia	Auditor Time	-
	17:00	All	Closing meeting	-

Remote auditing, translation and multiple auditor streams: Client confirmation that the above multiple auditor streams and/or audit language / translation arrangements and/or remote auditing arrangements are accepted and can be supported with client resources/IT infrastructure:

Information security measures agreed with client:

Client Representative Name: DEREK LAMB Client signature/email: Date : 26/10/2020

This audit may be conducted in English/Local language but would be reported in English unless otherwise stated. BSI maintains strict confidentiality concerning all information gained from undertaking its business (A copy of the auditors onfidentiality statement is available upon request).

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Audit Plan Type: Surveillance Audit			**Report (SMO) Number & plan Rev No: 3000497 rev 0**
Client	Viamed Ltd		
Address and locations	15/17 Station Road, Cross Hills, Keighley, BD20 7DT, United Kingdom		
Audit Criteria (*policies, procedures or requirements including applicable certification standards and regulatory requirements*)	ISO 13485:2016 Viamed QMS BSI T&C		
Audit Scope	MD 78787 ISO 13485:2016 [UKAS] exp 25/2/2022 Service of Supra-Maximal Peripheral Nerve Stimulator, Simulation Equipment, Infant T Piece Resuscitators, Apgar Timer and Resuscitation Cabinets. Distribution and Service of electromedical devices		
Audit Objective	To conduct a surveillance assessment to determine the continued effectiveness of implementation of the company's management system, in accordance with the company objectives, policies and procedures, the management standards and applicable regulatory requirements from relevant regulatory authorities & BSI Conditions of Contract. To ensure that all requirements are covered during the certification period and to determine whether a recommendation for continuing certification to ISO 13485 certificate can be made.		
Opening Meeting Date / Time	13 Oct 2020 / 09h00	**BSI Team and accompanying personnel:**	
Closing Meeting Date / Time	13 Oct 2020 / 17h00	Leader	Antonio Di Noia
Company Representative	Mr Derek Lamb	Member(s)	-
Date Plan submitted to Client	14 Sept 2020 (e-mail)	Others	-
Audit Language	English	*Translation Arrangements: Not required*	

Remote Audit	☒ Full ☐ Partial *(Specify in plan)*	**ICT used, including client IT security / confidentiality measures**	Remote auditing techniques used (e.g. email, phone, web-call, screen share, client system, client video, smart glasses) Areas covered by remote auditing: ◦ Audit preparation re: personnel and documentation required according to audit plan ◦ Submission of information / documentation in advance via agreed transfer mechanism (e-mail, FTP, encryption) in accordance with the agreed information security arrangement ◦ Access to client management system, documented information and records using client defined access control in accordance with client information security policy