Viamed.

Minor (5) nonconformities arising from this assessment.

Finding Reference	1826110-201909-N1	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	**Clause**	
Category	Minor		
Area/process :	Essential Assessment Information: QMS System Review, QMS, Business, Product & Process Changes and Improvements Objectives and Targets Management Responsibility and Changes: 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 8.1, 8.5.1		
Statement of non-conformance:	Auditing Organization Logos within the QMS documentation (Certificate of calibration of the Tom Thumb and EyeMax2TM Phototherapy Eye Masks web site leaflet) have not been correctly used.		
Clause requirements	BSI Terms and Conditions of Contract 13. The licence in clause 12 includes the display of any accompanying BSI logo or third party logo for which BSI has a licence to permit such display (and Client shall only display it in accordance with such third party's terms) and which is relevant to the services at Client's site, on Client's products or broadcast in any manner for so long as the relevant certificate remains valid. Client may not sub-license or transfer the right to display any certificate issued by BSI, BSI logo or third party logo to any other party. Client may not amend the content or change the appearance of the certificate or the BSI logo. The licence in clauses 12 and 13 ends on expiry or termination for any reason of the Contract or relevant certificate.		
Objective evidence	The BSI Assurance Mark used has still the old appearance and it was seen linked to a ISO 13485:2003 scheme		
Cause			
Correction / containment			
Corrective action			

We have kept old leaflet + letterhead as we don't like throw things away: This has caused us to use old BSI logos. Using old stock didn't review logo ~~Should have monitored~~ Remove all old leaflets + letterhead from company so it cannot be used. Issue set company wide to get rid of all stocks. Regular reviewed paper stocks leaflets + letter head for correct logo.

#7941 will add rolling issue annually to check paper + web for correct logo + date

Finding Reference	1826110-201909-N2	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	**Clause**	7.5.11
Category	Minor		
Area/process :	Operations, Calibration [Service and Distribution (picking and packaging)]:		

the Grease and Sealent used is the workshop was not Renewed regularly to ensure it was not going past its ~~life~~ useable life span with it not looking on use, by doing this we missed Renewing the products and checking their data sheets for a manufacturers life span of product.

Statement of non-conformance:	The product preservation is not fully effective as no process was seen in place to ensure that the chemicals (grease and sealant used respectively for the lubrication and to lock the regulator screw of the Tom Thumb infant resuscitator) were used within their lifetime.
Clause requirements	Preservation of product The organization shall document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation shall apply to the constituent parts of a medical device. The organization shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by: a) designing and constructing suitable packaging and shipping containers; b) documenting requirements for special conditions needed if packaging alone cannot provide preservation. If special conditions are required, they shall be controlled and recorded (see 4.2.5).
Objective evidence	Fomblin OT20 Grease 110gm tube internal ref 0330220, MH052 Thread sealant internal ref 0330237
Cause	
Correction / containment	
Corrective action	

we are going to add regular issues to check Data Sheets on products used for lifespan and dispose of when it reaches what the manufacturer states is estimated shelf life.

have regular reviews and issues to make sure that all products like these, are looked at regularly and disposed of when past their shelf life. * used in production or servicing

These will be Audited as well to check compliance

Add to Audit 11 Q11 added #154976

we will update all Relevant Procedure

Issue sent to Mg #154976

50.05, 50.06, 50.07, 50.16, 50.18, 50.19

Tom Thumb QA pro VMGOP 50.13 #154980

50.03.2, 50.02, 50.01, 50.04

Finding Reference	1826110-201909-N3	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	**Clause**	7.4.3
Category	Minor		
Area/process:	Operations, Calibration [Service and Distribution (picking and packaging)]: 7.5, 8.3, 8.4, 4.2.4 , 7.6		
Statement of non-conformance:	The verification of purchased product is not fully effective as procedure for the incoming inspections was seen requiring verification activities to be perfromed and verified against acceptable limits, however no limits were seen defined.		
Clause requirements	Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the		

we did not have a suitable test/QA procedure in place for the testing of the MD300 oxywatch.

Correct the Relevent procedure. add issues to make sure if procedures are missing or not suitable they are Reported back to management

add rolling tasks to make sure reviewed regularly.

Review all procedures of incoming stock so we can check their suitability + put issues in place to remind staff + review.

Put system in Intrustrits to monitor incoming goods and their procedures.

	purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5).
Objective evidence	MD300 QA Procedure for OxyWatch Fingertip Pulse Oximeter .
Cause	
Correction / containment	
Corrective action	

Finding Reference	1826110-201909-N4	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	**Clause**	7.1
Category	Minor		
Area/process :	Operations, Calibration [Service and Distribution (picking and packaging)]: 7.5, 8.3, 8.4, 4.2.4 , 7.6		
Statement of non-conformance:	The risk management process is not fully effective as no linkage was provided to the verification activities of the risk control measures and the assessment of risks before and after mitigation were not clearly defined.		
Clause requirements	Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement,		

no specific Risk assessment was in place for the service and production of the tom thumb. it should have been added to the production & service procedures QA.

write an up to date Risk assessment for all stages of the production, serv + QA of the tom Thumb. we no longer produce this item. But for thoroughness we will make the Risk assessment cover all areas so we do not miss anything.

check all production, servicing, QA areas/procedures for an up to date Risk assessment. verify they are fit for purpose and easily accessable to staff. add to Required Reading to make sure they have been Read.

#155069

	inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteriafor product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971.
Objective evidence	Risk of Assembling or Servicing a Tom Thumb issued 30875
Cause	
Correction / containment	
Corrective action	

Finding Reference	1826110-201909-N5	**Certificate Reference**	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	**Clause**	6.2
Category	Minor		
Area/process :	Human Resources, Competence, Awareness and Training: 6.1, 6.2		
Statement of non-conformance:	Training is not fully effective as there was no documented requirement to evaluate the effectiveness of the training given and no clear process was in place. Further there were no evidences of this been proportionate to the risk associated with the work under for which training is provided.		
Clause requirements	Human resources Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and		

we do not have a specific process in place to evaluate the training that is given above if and ~~when~~ is effective.

	experience (see 4.2.5). NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.
Objective evidence	VOP 12 Training issued 23527
Cause	
Correction / containment	
Corrective action	