QC 21 Non Conformance Report

Date	24/09/2019
Issue id unique identifier	**155084**
BSI Ref (if applicable) unique identifier	1826110-201909-N3
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	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.
Investigation By: Person responsible	Derek Lamb
Investigation Issue id (if applicable) Root Cause Analysis	We did not have suitable QA / test procedure, in place, for the testing of the MD300 Oxywatch. The product in question is an OEM product, carrying its own CE mark. In the past we had a few Dead on Arrival failures with this companies products. So a Go – No Go QA test was introduced, so we could deal with failures immediately and not have the end users be affected. This QA procedure incorrectly implied we should be taking or at least ensuring suitable readings without a means of accurate measurement.
Corrective Action By: Person responsible	Derek Lamb

Corrective Action Issue ID (if applicable): Relevant and Proportionate Corrective Action	Process ID 7942 Issue ID 156113 Issue ID 156100 Issue ID 155531 Issue ID 154997 Issue ID 154996 Issue ID 154995 Issue ID 154994 Issue ID 154994 Issue ID 154993 Issue ID 154992 Issue ID 154991 Issue ID 154644
Time Scale for Corrective Action Time for completion of all identified actions	Immediate Action to be completed by 19th October 2019 Corrective action to be completed by 19th October 2019
Corrective Action:	**Immediate Action** We will correct the relevant procedure and add issues to make sure, if procedures are missing or not suitable, they are reported back to management. We will discuss with all relevant staff, the importance of having the correct, up to date procedure for each incoming product. So they can verify these, whenever they process stock coming in to the building.

	Any procedures that need to be updated will be done immediately. **Corrective Action** Review all procedures of incoming stock so we can check their suitability. We will put issues in place to remind staff and review regularly. A new process will be added in to Intrastats, which will generate the requirements of all the processes eg. Risk Assessments, Measurable Objectives and Training Requirements. This will generate Rolling Task, Rolling Issue and Rolling Audit Task. We will put a system in to Intrastats to monitor incoming goods and their procedures. To check if they are present and when they were last reviewed. The rolling tasks and audits will ensure these systems and procedures are reviewed regularly.
Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	
Closed By:	
Closed on	7/8/2022