Section 1 – This section is a listing of the auditing organization and the auditor.

Section 1. Audit Information		
Auditing Organization: DEKRA Certification B.V.		
Audit Start Date: 2021-06-07	Audit End Date: 2021-06-09	Duration of Audit: 2.5 Days
Audit Report Number: 1234567	Language used during Audit: English	
Team Member: BJ Johnson, Lead Auditor, DEKRA Employee		

Section 2 – This section is the information on the medical device manufacturer and the registration numbers for the relevant Jurisdictions. In this case the manufacturer is only asking for Australia and Brazil.

Section 2. Audited Facility				
Name: My Medical Device Company		MDSAP Facility Identifier: 00-000-0000		
Street Address: 222 Main Street				
City: Anywhere	Country: USA	State: Indiana	Zip Code: 12345	
Contact: Jane Doe	Title: Quality Director	Email: jane.doe@MMDC.com	111-222-3333	
Senior Management: Bob Smith, CEO				
Facility Identification Numbers				
Australia: 000 000 000	Brazil: 80000000000	Canada: NA	Japan: NA	US: NA
Other: NA				

Section 3 – This section will cover the type of audit, the scope of the audit and the relevant regulations and standards.

Section 3: Certification Schemes, Scope & Criteria, Audit Types
MDSAP Certification Scheme
Audit Type: Recertification
Scope of certification: Design and manufacture of wound care dressings
ISO 13485:2016
Australia: Schedule 3, Part 1 – Full Quality Assurance System
Brazil: RDC ANVISA n. 16/2013 – Good Manufacturing Practices RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009 Vigilance
Canada: NA
Japan: NA
US: NA
CE Marking: NA
Other: ISO 13485:2016

Section 4 – This section covers some basic questions on the manufacturer and how many sites are covered with the certification and will be audited.

Section 4. 4. Certification Holder and Multi-site Organization
Certification Holder
Is the Audited Facility the certification holder, as identified on the certification documents? No
Campus
Is the Audited Facility part of a campus including buildings at different addresses that were also visited during this audit? No
Does the scope of certification cover sites other than the Audited Facility? No
Related sites audited as part of the scope of certification (audit outcomes must be documented in separate reports) No
Corporate Information
My Medical Device Company, hereafter referred to as MMDC, develops, manufactures, and distributes wound care dressings that are sold to hospitals. The company was founded in Indiana in 2000. The scope of this audit covers the wound care products marketed under the brand name Band-It. The facility is located on approximately 10 acre plot of land with 1 building. The building is approximately 50,000 sq. ft.

Section 5 – This section covers the objectives to be met by the audit.

Section 5. Audit Objectives
Audit objectives shall include as applicable: Recertification audit: evaluation of: • the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements; • product/process related technologies (e.g. injection molding, sterilization); • adequate product technical documentation in relation to relevant regulatory requirements; and, • the manufacturer's continued fulfillment of these requirements.

Section 6 – This section contians information on how the site is registered in each jursidiction and what aspects of the QMS are conducted at the facility

Section 6. Audited Facility Description
Regulatory Roles played by the Audited Facility, considered in the scope of the audit
Australia: Manufacturer
Brazil: Manufacturer
Activities at the Audited Facility
Design and Development, Purchasing, Management (regulatory affairs), Monitoring and Measurement (verification of purchased product /processes, product), Monitoring and Measurement (Final product release), Production (in-process, other than sterilization), Production (packaging / labeling), Preservation (storage / delivery), Production (finished device) Other, specify: NA

Activities taking place at that address that are not included in the Scope of Certification (NA if none): NA		
Number of staff: 55	Number of shifts: 2	Number of staff working in shifts: 10

Section 7 – This section lists the name and addresses of the critical suppliers. In this section there will be an address, the components or service supplied and if audited as part of this audit. (these items are not added here, but can be seen on the original form.

Section 7. Critical Suppliers
Organization : American Weaving
Organization: Gamma Sterilization Corp.

Section 8 – This section contains the past audit numbers as well as what type of audit they were and the numbers of nonconformances.

Section 8. Audit History
2018
2019
2020
There have been no nonconformities in the past audits.

Section 9 – This section lists the exclusions and Non-applicable sections of the QMS.

Section 9. Exclusions and Non-Applications of Requirements in the QMS
Exclusions: NA Non-Applications: 7.5.3 Installation and 7.5.4 Servicing

Section 10 – This section would list any activities conducted before the audit, examples would be review of Quality Manual if asked for pre-audit.

Section 10. Outcome of Pre-Audit Activities (including Stage 1 as applicable)
NA

Section 11 – This section is the main part of the audit report, and has 8 individual sections for each of the MDSAP chapters. Below I have only copied the audit report text and have highlighted in yellow where the Nonconformances were noted. The actual non-conformances are listed in Section 12.

Section 11. Audit Findings
Section 11.1 - Process: Management
The focus of the audit was on the requirements for management processes according to ISO 13485:2016 § 4.1, 4.2.1, 4.2.2, 4.2.4, 4.2.5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 6.1, and 6.2.

Task 1
QMS Planning, Implementation, Changes and Quality Manual
The MMDC quality management system is documented per Quality Manual. This Quality Manual has not been updated since the last audit. The quality manual contained the proper regulatory jurisdictions in scope. It was verified that quality management system planning is performed and that all changes to the QMS are managed and properly documented.

Task 2
Management Representative
Top management has clearly documented the appointment of the Management Representative as Jane Doe per her job description, Job Description, Quality Director, 15 Feb 2018 and the Management Representative Memo of Authorization, 2 Feb 2018. The job description contained requirements for ensuring the QMS is established and maintained, reporting to top management on the performance of the QMS, and promotion of regulatory requirements throughout the organization.

Task 3
Quality Policy and Quality Objectives
The Quality Policy, was recorded under SOP 5.3 and has not updated since last audit. The Quality Planning, 2020 Objectives and 2021 Objectives were all reviewed. Objectives were noted as:
- Complaint rate less than 30% of sales
- Nonconformance rate less than 40%
- Scrap rate under 20%

The documents showed that objectives are measurable and consistent with the quality policy. The 2021 objectives also showed that 2020 objectives were either closed as completed or were moved to 2020 as needed.

The quality policy and objectives are communicated throughout the organization with the completion of training to the procedure and procedure. The training file for Jane Doe was reviewed as evidence of this training having been completed.

Task 4
Organizational charts and job descriptions were reviewed to ensure they include provisions for responsibilities, authorities, resources, competencies, and training. Job descriptions reviewed included:
- Quality Director
- Operations Director

During the review of the job descriptions it was verified that specific requirements for those jobs were accounted for by the responsible person filling that position.

Task 5
Extent of Outsourcing
Outsourcing of processes for MMDC includes raw materials, sterilization processing, and contract laboratories. This was verified to have been properly documented, see Section 11.7 below. Samples of 2 quality agreements for actions not performed by the MMDC manufacturing facility were reviewed for the following:
- XYZ Sterilization
- America Weaving

The agreements were found to be in compliance with the local regulations.

Task 6
Personnel Competency and Training
MMDC has established and maintains procedure SOP 6.2 governing the process of competence and training and it remains at the same revision as last audit. The training procedure contains the need for a training plan, training curricula, descriptions of methodologies and format, minimum requirements, execution, and need for effectiveness verification, retraining, and documented records. The training program is an electronic system called SAP. Procedural training are automatically sent via the system when a procedure is updated per the training curricula that is entered into the system. It was explained that the curricula is determined by job function and is under the control of the managers. Training files reviewed for this audit include:

- Jane Doe, Training Record
- Bob Smith, Training Record

Task 7
Risk Management Planning and Review
During discussion with the Management Representative is was noted that risk management is embedded in the individual procedures, such as CAPA, change control, and design control. During the review of each procedure a review for the need for risk management was completed, there were no gaps noted. Suitability is reviewed through management review, which assesses the top 3 risks at site level and corporate level. Resources are also assessed during management review and top management meetings.

Task 8
Document and Record Controls
MMDC has established and maintains procedure SOP 4.2 governing the process of document control and significant/substantial change reporting, which has not been updated since the last audit. The Management Representative explained that the electronic system that is used for documents and document control is in the process of migrating to One Vault, a new system.

Record retention is located in SOP 4.2.5 and was updated recently to include minor updates for the MDR transition. Record retention periods were found to be acceptable. Records are maintained mainly in the electronic systems they are in and are retained indefinitely within those systems.

Along with this Form 4.2.1, Change Requests was reviewed. The procedures contain the need for an approval by the document owner and quality management prior to use, periodic review, and approvals by the same sites and functions that originally approved the document. The change orders (CR) include, description of change, reason of change, evaluation of the impact of change and if regulatory notification is required. The following CRs were reviewed in this audit:

- CR-001
- CR-003
- CR-006

Electronic record backups process are controlled by SOP 9, which is at the same revision as the last audit. In section 5.1 it explains generally about how backups are handled and section 5.6 discusses

retention periods. It was confirmed that the data center replicates the backups and the data is stored in two places to assure proper retention.

Task 9
MMDC has established and maintains procedure SOP 5.6 governing the process of organization structure, quality policy, quality objectives, and management review. SOP 5.6 was reviewed and updates to the current revision include the need for management output to include the setting of new complaint trending action levels. The procedure was confirmed to have frequency of reviews at a minimum once a year, required attendance, proper inputs/outputs, included a review of quality policy and objectives, and ensures that the review will show that the QMS is effective. The last management review was verified to have been conducted in Jun 2020. June 2020 Management Review, dated 18 Jun 2020 and the accompanying slides, dated 18 Jun 2020, were reviewed were noted to have included all applicable regulatory requirements. It is verified that the management reviews are conducted per the required frequency. Also, the Attendance Log, dated 8 Jun 2020 was verified to have the proper attendees. The review contained slides that discuss the review of the quality policy, quality objective, and suitability and effectiveness of the quality management system. The 2020 slides were reviewed to assure they contain the 2019 action items. The next review is scheduled for 21 June 2021.

Task 10
MMDC has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorizations are distributed with the procedure SOP 7.2.3. This procedure has been updated recently for minor changes.

It was verified that all appropriate markets are discussed in this procedure including, Australia and Brazil, and that Regulatory Affairs is responsible for device registration and listing. During the last audit, market authorizations were only held in the Brazil, since then market authorizations have been obtained in the Australia. Plans are to add the US and Canada within the next year. Further detail on product approvals is contained in Section 11.2 below. It was verified via interview of the Management Representative that sales in the past year were only to approved markets.

Controls for shipping and distribution are documented on Form 122 and the product supply agreements which are stored in the site's electronic document management system. During an interview with the Management Representative it was noted that the inventory management system contains a control that blocks sales to countries that are not approved for sale on product distributed by MMDC. Band-It products are distributed directly by the company. The sales data for Band-It products was reviewed. It shows that sales were made only to Australia and Brazil and sales have not been made outside of that jurisdiction.

Task 11
Conclusion
A review was conducted of all the tasks associated with the Management sections of the audit. It is concluded that Top Management has demonstrated the necessary commitment to ensure a suitable and effective quality management system is in place and being maintained and to ensure the effectiveness of the system has been communicated to personnel.

Nonconformity: No

Section 11.2 - Process: Device Marketing Authorization and Facility Registration

The focus of the audit was on the requirements for device marketing authorization and facility registration according to ISO13485:2016 § 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, and 7.3.9.

Task 1 and 2
Procedure SOP 7.2.3 manages the market authorization and facility registration process for the Australia and Brazil. Sales are not currently completed for Canada, Japan, and the US. The procedure does require proper registration in the MDSAP markets prior to sale of products, as well as review of changes to approved devices as to whether they are significant and would need to be reported to the specific countries where approval is held. Below is information on specific MDSAP regions.

Australia
Registration has been completed for Australia and the Certificate of Inclusion in the Australian Register of Therapeutic Goods has been received, certificate name/number. It was confirmed that product has not been sold into Australia OR The following products are registered in Australia:

- Part #1124, DOC001 dated 1 Jan 2016, ARTG 1234, Class III, Active, Band-It Regular
- Part #1125, DOC002 dated 1 Jan 2016, ARTG 1235, Class III, Active, Band-It Large

Product was verified to have been classified correctly per the Australian rules and this is located in Procedure for classification using Australian classification rules. Procedure updates.

The conformity assessment process is documented in Procedure for conformity assessment. Procedure updates. Verification of the conformity assessment was completed by Discuss conformity assessment route used and document if DEKRA cert was used.

Product sales in the Australia for the past year were reviewed and found to have been only that which are cleared for sale into Australia.

The site has contracted AUS SPA as it Australian Sponsor. It was verified that there is a contract with AUS SPA for the Band-It products, that was signed in 11 Nov 2015. It was also verified that the company is controlled through suppler controls and is on the MMDC Approved Supplier List. SOP 7.2.3 controls the process for marketing authorization process and sponsor selection and maintenance. The contract with AUD SPA name, was reviewed and was found to contain annual reporting specifics for high risk devices, complaint reporting, adverse event reporting, advisory notices, and recalls. It also contains a statement that permits the TGA to inspect, take documents, and conduct tests on products from MMDC.

Brazil
Brazilian registration was completed, and the following products are registered/notified in Brazil:

- Part #1124, Notification or Registration, Class III, Band-It

Product sales in the Brazil for the past year were reviewed and found to have been only that which are cleared for sale into Brazil.

It was verified that procedure SOP 7.2.3 that MMDC will designate a domestic manufacture or importer (legal Representative) before device sales will commence in Brazil and registration is required. The Establishment license 80000000000 was reviewed during the audit, and records the importer as Importer name and location.

Canada
It was confirmed that MMDC is not registered in Canada and no products have been shipped to Canada.

Japan
MMDC has not obtained Japanese registration, and it was verified that no products have been sold there.

USA
MMDC is not registered with the US FDA and it was verified no products have been shipped to the US.

Task 3
Changes to devices and their evaluation and reporting to regulatory bodies are managed by the procedure SOP 4.2.4. This procedure was updated after the last DEKRA audit to include the Australian regulations. The procedure discusses the definitions for both significant and substantial changes and specific requirements for reporting to the Australia and Brazil.

The reporting decisions for the applicable authorities are documented on Form 4.2.4.1.1. The process for reporting to the authorities is documented in procedure 4.2.4.1. The form contains a check completed by regulatory affairs of regulatory/notified body notification.

The following change orders were reviewed for the determination of the requirement for significant and substantial changes and notification and to verify the proper approvals per procedure. During the review it was deemed that notifications were made for significant and substantial changes when necessary.

- Change Record CR-001
- Change Record CR-003
- Change Record CR-006

Nonconformity: No

Section 11.3 - Process: Measurement, Analysis and Improvement

Data would be entered here that covered CAPA, Nonconforming Product, Internal Audit, Complaint handling, and recalls and Post Market Surveillance. For the sake of the NC only the section on Complaint management was completed. The other task numbers are listed however no data was entered.

The focus of the audit was on the requirements for measurement, analysis, and improvement according to ISO13485:2016 § 7.1, 7.2.1, 7.2.3, 8.1, 8.2, 8.3.1, 8.3.2, 8.3.3, 8.4, and 8.5.

Task 1 and 2
Procedure for MAI of QMS Effectiveness and Product Conformity
Sources of quality data

Task 3
Investigation of Nonconformity

Task 3, 4, 5, 6, 7
CAPA

Task 8 and 9
Control of Non-Conforming Product

Task 10
Internal Audit

Task 11
Information Supplied for Management Review

Task 12, 13, 14, 15
Customer Feedback and Communication: Complaint Handling and Advisory Notice / Regulatory Reporting
PMS
MMDC has established and maintains procedure 8.2.1 governing the process of Post Market Surveillance. The procedure has been created to provide a system to actively review experience gained from products in the post-production phase and record and analyse that data to draw conclusions on the life-cycle risk management process of those products. Minor changes were made to this procedure since the last audit, mainly to add back the MDD specific sections, as those were removed prematurely when planning for MDR transition. The procedure contained reference to all MDSAP countries in scope.

The one (1) post market surveillance plans were chosen for review. The plans could be accepted as recorded.
• PMS001 plan/report

Recalls and Advisory Notices
MMDC has established and maintains procedure 8.2.1.1 governing the process of recalls and advisory notices. It was not updated since the last audit, and was reviewed. The procedure contains the process for recalling product and issuing advisory notices for all MDSAP markets. It was verified by interview of the title that there have been no recalls or advisory notices for product since the last audit, and no indications were noted that this was incorrectly implemented.

Complaints
MMDC has established and maintains procedure 8.2.2 governing the process of complaint handling. It was reviewed and had minor changes since the last audit. The procedure describes the process of how to receive, classify, evaluate, investigate, take action if needed, and close the complaints. Complaint records are maintained via the electronic document control system and are retained. Complaint files contain a unique complaint number, information on the person making the complaint, device information, a summary of the complaint, evaluation, action taken, adverse event reporting decision, and a closure summary.

The complaint log showed that there were a total of four (4) complaints received since the last audit, all complaints were reviewed. Complaint files that were reviewed contained a clear notation of when the complaint was received and when the reportability decision was made.

Complaint files are not used as an input to the risk management process and do not contain a section to record how the information from the complaint may or may not affect the risk analysis files. See AR01-Minor01 below for more detail.

Complaint files reviewed are noted below:

- C20-001
- C20-002
- C20-003
- C21-001

Nonconformity: Yes, see number AR01-Minor01 below

Section 11.4 - Process: Medical Device Adverse Events and Advisory Notices Reporting

The focus of the audit was on the requirements for adverse event and advisory notices reporting according to ISO13485:2016 § 7.2.3, 8.2.2, 8.2.3, and 8.3.3.

Task 1 and 2
The requirements for adverse event reporting are located in procedure Procedure 8.2.3. The procedure has not been updated since the last audit. The procedure contains requirements for adverse event reporting in both Australian and Brazilian markets. There were no adverse event reports made to any regulatory authority since the last audit. Reporting decisions in complaints that were reviewed could be accepted by the auditor.

Nonconformity: No

Section 11.5 - Process: Design and development

The focus of the audit is on the design and development process according to ISO13485:2016 § 7.1 & 7.3.

Task 1 and 2
Identification of devices subject to design and development procedures; technical documentation
Selection of a completed design and development project
MMDC has established and maintains procedure SOP 7.3 governing the process of design control. The design and development files are maintained in an electronic document system SAP and include the process for approval via electronic signatures. The procedure also contains reference to address incomplete, ambiguous, and conflicting design input requirements. There have been no new design and development projects since the last audit at MMDC nor have there been any changes to the Band-It products. This section will cover a review of the procedures to assure compliance with the scope of the audit.

Task 3
Design and development planning
The design and development planning is completed using Form 7.3.2. The form was reviewed and found to contain the project stages, planned design reviews, planned verification, planned validation, planned design transfer and the assignment of responsibilities for the design and development team, including an independent reviewer. Approval section of the form contained functions per the procedure.

Task 4
Implementation of the design and development procedures
It was verified that the SOP 7.3 addresses D&D states, review, verification, validation, transfer and changes.

Task 5, 6, 7

Design Inputs and Outputs and Design Verification

The design inputs per SO 7.3 are completed in 2 phases. The first phase is the use of the form for User Needs, Form 7.3.3.1. This form is completed by Marketing and design control lead to gather and document the data received from customers and users. The documentation of the user needs included risk based ratings used in the design control process. Approvals by marketing, design and development, quality, and manufacturing are required.

For the second phase this data is entered into the form Design Traceability Matrix (DTM), Form 7.3.3.2. The DTM contains both the input and output data for the product.

Task 8
Risk Management
Risk management is based on a risk management plan, and Band-IT Risk Management Plan, was reviewed. From this plan records were starting with a clinical hazards list, and from that the design FMEA and Application FMEAs were created. It was noted that risk management is planned to be completed semiannually for the 1st 2 years and then annually after that. The following documents were reviewed and found to show risk management activities are defined and implemented for the product.

- Band-It RMP, dated 11Nov 2020
- Band-It RMR, dated 11Dec 2020

Task 9 and 10
Design Verification and Validation
It was noted that SOP 7.3 requires verification and validation work are completed per the design plan and assured that risk control measures are effective in controlling or reducing that risk. The procedure also reequires that design outputs meet the inputs noted on the DTM.

Task 11
Clinical studies were not conducted on the product as there were past studies done on similar products, Band-It Small. The rationale for this use was documented in Band-It RMR, 11 Dec 2020, and were found to be acceptable.

Task 12
Software Design and Development
There is no software in the Band-It devices.

Task 13
Design and Development Changes
It was noted that design changes that are conducted during the design and development process are captured within the process in SAP using a change log. There were no changes noted on the change log. The change control process was shown above to contain the proper steps for notifying the correct regulatory agencies.

Task 14 and 16
Design Review and Transfer

Design reviews are conducted at the steps defined in the design plan. Design changes are captured in the change control process. SOP 7.3 requires final release of the product to be done after the design transfer process.

Task 15
Design Changes effect on previous products
No changes have been made to this product since product release.

Nonconformity: No

Section 11.6 - Process: Production and Service controls

The focus of the audit was on the requirements for the production and service provision according to ISO13485:2016 § 6.2, 6.3, 6.4, 7.1, 7.2.2, 7.4.3, 7.5, 7.6, 8.3.4, and 8.3.

Task 1 and 3
Planning of production and service process
Controls for the implementation of selected production and services process(es)
Production processes are planned, and production activities are performed under controlled conditions including the following:

- Documented work instructions providing step-by-step instructions for manufacturing and test processes
- A manufacturing router identifying the part number, revision level and description, lot number, required process steps, related procedures or work instructions and current revision level, required materials and equipment
- Forms for documenting production activities, traceability of materials used, equipment used, setup and operating parameters for processes and equipment, calibration status of measuring equipment
- Validated production processes with defined process parameters
- Defined acceptance criteria and calibrated measuring and test equipment
- FMEA documenting process risk management activities
- Product labeling documenting the gas composition, batch number, and expiration date
- Qualified personnel

Task 2
Band-It production for Large was in process at the time of the audit. As there is only one (1) process for the production of the Band-It products, the only difference is in the die used to cut the dressing to size, this was selected for review.

Tasks 4, 5, 6
Control of Product Cleanliness
Infrastructure
Work Environment
Product cleanliness is completed by purchasing medical grade raw materials that are manufactured in cleanrooms and are free from particle shedding materials. In addition the machine that is used to die cut and assemble the bandages is contained within a controlled environment. Procedures for this process are Number, Rev , Title.

Infrastructure
MMDC has established and maintains procedure 6.3.1 for equipment maintenance. The procedure has not been updated since last audit.

The Preventive maintenance log is reviewed monthly. If maintenance is required a work order will be assigned to a technician for completion. Once completed a new form with the next due date will be started to prepare for the next maintenance to be done. Records are maintained by piece of equipment and are kept for a minimum of six years. The following preventive maintenance files were reviewed based on those found the Band-It production area.
Cleanroom HVAC System (performed every 6 months)

- 6 month check 26 Jan 2020
- 6 month check 26 Jan 2020

Die Cutting Machine DC-001 (performed yearly)

- Monthly check 26 Jan 2020 through 26 Dec 2020

It was found that there were no yearly maintenance records for DC-001 in 2020, monthly maintenance was completed. See Nonconformance AR01-Minor02.

The site infrastructure was verified to ensure that the manufacturing facility is configured in order to provide adequate means for people flow.

Work Environment
MMDC has one certified cleanroom. MMDC has established and maintains procedure SOP 6.4.2 for the cleanrooms/ controlled environments. The procedure has been updated since last audit for minor clarifications

WI 6.4.2.1 discusses good sanitation and health habits and that if persons have a condition that could affect the safety of the product they will remain out of production until fit for work. IT also includes good sanitation and health habits, including abstention from eating, drinking, or smoking in areas designated for production, storage, and quality control testing.

WI 6.4.2.2, which was revised since the last audit updated for new rodent trap locations, calls for rodent traps on outside and inside, and that insecticides are used only in the office and kitchen and not on production floor. Monthly reports are received and reviewed for completeness and then maintained. The following pest control reports were reviewed, 16 Dec 2020 and 26 Aug 2020 and found acceptable.

Tasks 7 & 8
Process Validation
Process validation is controlled by the procedure SOP7.5.5. The procedure has been updated since the last audit for minor updates for clarity. The procedure includes information on how to conduct a validation. A validation plan is required. Revalidation is a consideration and will be located in the report. The site has a Master Validation Plan for the Band-It products. The plan clearly documents when a validation is required or not required and if validation is not required, what type of inspection is completed to assure it is verified.

For process validation files were chosen from the master validation plan for the system. The validation included an IQ, OQ, and PQ. The following documents were reviewed:

- Band-It Sealing Validation

Raw data was found to show who performed the validation. It was found that the validation was performed by two individuals, one who was the author of the validation and another manufacturing engineer.

The maintenance for the Doboy sealer, was reviewed to determine if there had been any significant changes to the system since the validation. It was found that there were none. The validation files were found to be acceptable.

Task 9
Validation – Sterilization
The products are sterilized using gamma radiation. MMDC has established and maintains procedure 7.5.5 governing the process of sterilization. The procedure requires that quarterly dose audits be conducted as well as an annual assessment of the need for revalidation per procedures 7.5.5. Bioburden samples are taken during the quarterly dose audits. A drastic change in number and type of organism, a new component, or a change in sterilization aspects could result in a new validation being needed.

Verification and dose audits are conducted at the proper dose was checked by reviewing Report 001, Rev 4, Final Report- Dose Setting Procedure Using Bioburden Information of Band-It products. The validated dose was verified to have been the same as that used in the dose audits. The following dose audits were reviewed during the audit and found acceptable:

- Q1 2020, Band-It Q1 Dose Audit
- Q2 2020, Band-It Q1 Dose Audit
- Q3 2020, Band-It Q1 Dose Audit
- Q4 2020, Band-It Q1 Dose Audit

Task 10 and 11
Process Control and Monitoring
Manufacturing controls were noted to have been put in place by MMDC using manufacturing procedures and the device history records. The manufacturing processes for the Band-It production was reviewed:

- SOP 7.5 Production Process
- WI 7.5.1 Product Packaging Process

The following validated process contain process monitoring controls in place, Optima Manufacturing Line Speed, Optima Manufacturing line Tension, Sealing Temperature, and Sealing Time. MMDC has established and maintains WI 7.5.1.1 governing the process control and monitoring of validated processes. The validation master plan was reviewed to determine which processes were monitored and the sealer monitoring was selected for review. The process monitoring was recorded on on the device history records or in binders located next to the equipment. It was verified that the processes that are monitored are determined based on the risk of the product and are linked to the risk management process. The following records were reviewed:

- Sealer Temperature
- Sealing Time

Task 12
Competence of personnel
Name has established and maintains procedure SOP 6.2 governing the process of competence and training. Training files for production personnel reviewed for this audit include:

- E. Smith, Training File
- T. Johnson, Training File

- P. Piper, Training File
- W. Miller, Training File

Files were verified to have had training to the procedures that are specific to each person's job functions. Training files can be accepted as accurate and complete.

It was noted that production area cleaning was conducted by an outside service and approved supplier, WeClean. Training records for J. Doe and M. Smith for training on how to clean and gown for the cleanroom were requested as the most recent cleaning crew. The following items were reviewed:

• Cleaning Records from 1 Jan 2020 to 31 Dec 2020

Training records for MMDC employees can be accepted as accurate and complete.

Task 13 and 14

Control Over Monitoring and Measuring Devices

MMDC has established and maintains procedure SOP 7.6 governing the process of calibration. The calibration process is completed by contract calibration company Bob's Calibration Company (BCC). MMDC handles the tracking of calibration and will notify BCC when something is coming due for calibration. In addition the site requires all equipment number and calibration information on the Batch Record to assure only calibrated equipment is used. Calibration stickers were noted on all required equipment and were found to be accurate and up to date. The procedure take into effect the need to take appropriate action on equipment and product when it is found that equipment that was out of calibration was used. The following calibration records were reviewed:

- Equipment #25, Doboy Sealer Temperature Gage, 6 months, 3 Jan 2021
- Equipment #05, Manahelic Gage, 3 months, 3 Jan 2021
- Equipment #36, Caliper, 3 months, 3 Jan 2021
- Equipment #08, Ruler, 12 months, 3 Jan 2021

Calibration records were found to be completed per procedures and are acceptable to the DEKRA auditor. All equipment found was confirmed to be protected from damage and deterioration.

Task 15

Validation of software used for the control of the production and service process

Validation of software used in production is controlled by the procedure SOP 7.5.6. The procedure has been updated since the last audit for minor updates for clarity. The procedure includes information on how to conduct a validation and includes a section on software validation. A validation plan is required and will need to include software if that is necessary. Revalidation is a consideration and will be located in the report. The site has a Master Validation Plan for the Band-It product family. The plan clearly documents when a validation is required or not required and if validation is not required, what type of inspection is completed to assure it is verified.

For process validation files were chosen from the master validation plan for the electronic eye software on the Optima manufacturing line, which contains software. The software was validated as part of the process validation as it was off the shelf software that was not customized by MMDC. It was verified in Protocol #02 that the software was qualified with the process as there was no way to edit the system software. The following documents were reviewed:

- Software Validation report #456

Raw data was found to show who performed the validation.

Task 16, 17, 18

Device Master File, Production Record, Identification / Traceability
The Device Master Record - Band-It contains a bill of materials documenting the raw materials, labels, IFU inserts, patient cards, and packaging materials for the Band-It product family. The DMR includes a list of the suppliers that have been approved to supply these items. The DMR provides a list of applicable procedures required to manufacture, test, and package this product.

Task 18
Traceability applied to implantable, life-supporting or life sustaining medical devices
This section is not applicable as these devices are not life-supporting or life sustaining.

Tasks 19
Identification of product status
Product identification was noted during production tour. Products are either labeled or have proper documentation attached. Product identification clearly notes if product is waiting for inspection or testing or if it is released to the next step. QC lab approvals are noted on the DHR and were clearly marked for those items reviewed.

Task 20
Customer Property
There is no customer supplied property and no patient information was provided on the complaint files.

Task 21
Acceptance Activities
All acceptance activities and acceptance criteria are documented on the work order. Activities include visual inspection, seal verification, and leak testing. Each batch is inspected 100% for compliance to all criteria. Test equipment ID, variable data and acceptance (signatures) are documented on the batch records.

Tasks 22 and 23
Nonconforming Product in Production, Rework
Nonconforming products were clearly identified and stored in a quarantine area. Rework is not allowed per SOP8.3.2 in section 4.2. The procedure was updated since the last audit for minor clarification of responsibilities. The following NCRs were reviewed:

- NCR#20-01, 5 Jan 2020, Reason: Product dimension out of specification, Scrap, 5 Jan 2020
- NCR#20-10, 26 May 2020, Reason: Sealing temperature 1 degree F too hot, Use as Is, 18 Jun 2020
- NCR#20-98, 20 Dec 2020, Reason: Raw material failed tensile test, Return to Vendor, 10 Jan 2021

NCRs were handled properly per procedures and were found acceptable.

Task 24
Preservation of Product
Documented procedures for preservation of product during internal processing, storage and transport were observed. The procedures include SOP 7.5.11. The procedures require identification, handling, packaging, storage, and protection, including those products with limited shelf-life or requiring special storage conditions. The MMDC product was observed to have followed the procedure during processing. Special storage conditions were not noted for the Band-It devices. It was noted that

these conditions were maintained during production, storage, and shipping by monitoring of areas and shipping containers.

Task 25
Review of customer requirements, distribution records
MMDC has established and maintains procedure SOP 7.5.9 for customer requirements and distribution records. Approval of the purchase orders are conducted using SAP and the limits of who can purchase what is controlled within the system. It was confirmed that distribution records are also contained within SAP and are retained for six (6) years. The POs reviewed as part of the purchasing section below contained the name and address of initial consignee, product ID, quantity released, and control numbers used. It was found that production lot# B20200512 was released into inventory on May 13th, 2020 prior to the release of sterility and LAL test data, see nonconformance AR01-Major01.

Distribution process is maintained by MMDC for distribution worldwide. MMDC has completed quality agreement with Fed-Ex to define distribution requirements. Reviewed Internal quality agreement / Distribution Agreement with Fed-Ex. This was completed on 16 Jan 2016.

Any communication to regulatory authorities is managed by MMDC. This was reviewed as part of market authorization section of the audit and found adequate.

Task 26, 27, 28
Installation and Servicing
There is no installation and servicing for the Band-It devices.

Task 28
Risk controls applied to transport
There are no controls needed for product transfer as there are no special storage conditions noted for NAME.

Nonconformity: Yes, see numbers AR01-Major02 and AR01-Minor02 below

Section 11.7 - Process: Purchasing

Supplier Control data, including supplier selection, control, and revaluation would be supplied here. This section was not completed for this exercise, however the tasks are listed below.

The focus of the audit was on the requirements for purchasing according to ISO13485:2016 § 7.4 and 8.4.

Task 1, 2, 3
Planning, Procedures, and Selection of Supplier Files

Tasks 4, 5, 6, 7
Supplier Control, Selection, Monitoring, and Re-evaluation

Task 8, 9, 10
Adequacy, Requirements, Agreements, Documentation, and Verification of Purchased Products

Task 11
Data used in MAI process

Nonconformity: No
Section 11.8 - Other Findings Not
NA

Section 12 – This section is a listing of all the nonconformities found during the audit. Please review this section and think about based on your regulations what action would you expect to be taken by the manufacturer.

Section 12. Nonconformities			
NC Reference Number	Statement of Nonconformity / Supporting Evidence	ISO 13485:2016	MDSAP Grade Major or Minor NC
AR01-Major01	Release of product into inventory was not always done after planned arrangements had been completed. Production lot# B20200512 was released into inventory on May 13th, 2020 prior to the release of sterility and LAL test data. The LAL test was dated June 1, 2020 an sterility test report was dated June 5, 2020. SOP 10 requires all test results to be received and passed prior to release of product into inventory. It was verified that results all passed and product was not shipped until August 1, 2020.	8.26	4 Major
AR01-Minor01	The information gathered in the feedback process does not always serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. Procedure SOP 8.2.2, Rev A, Complaint Handling does not contain a link from complaints to risk management. In addition, complaint files reviewed did not show if risk management documentation was checked for either of those items. Files reviewed include: Complaint 20-22, 20-23, 20-24, 20-25, 21-01, 21-02.	8.2.1	3 Minor
AR01-Minor02	Required Preventive Maintenance was not completed on production equipment. The die cutting machine DC-001 was last maintained for yearly maintenance on 3 Mar 2019. Per WI 6.3.1.1, Rev E, Preventive Maintenance Die Cutting Machines, the maintenance is to be completed monthly and yearly. Maintenance records for the yearly maintenance for 2020 were not available. Monthly maintenance records were available.	6.3	1 Minor

Section 13 – This section contains any explanations of why the audit was not conducted to the audit agenda. This can include reasons like documentation was not available, major issues were found and the audit took longer than expected, etc. We also list any obstacles that were encountered such as cleanroom was not able to be entered or viewed from the outside, so no production was watched. Obstacles can cause an audit to be invalid.

Section 13. Significant Deviations from the Audit Plan		
There were no deviations from the audit plan		
Duration of the Audit	Planned: 2.5	Actual: 2.5
Obstacles		
There were no obstacles during this audit.		

Section 14 – This section will list how nonconformities from the last audit were verified and deemed closed.

Section 14. Follow-up of Past Nonconformities
NA

Section 15 – This section would list any major changes since the last audit, an example is a new cleanroom was built.

Section 15. Summary of Major Changes to Audited Facility
There have been no major changes to the facility.

Section 16 – This section lists all the conclusions to the audit and any actions to be taken.

Section 17 – This section lists any attachments that are added to the audit

Section 18 – This section is the approval signature.