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| **BMR FOR CATGUT SUTURE** | | | | | | | | | | | | | | | | | | | | | | |
| 1. **NEEDLE ATTACHMENT:** | | | | | | | | | | | | | | | | | | | | | | |
| CODE NO.: | | | |  | | | | | | | START DATE & TIME: | | | | | | |  | | | | |
| LOT NO.: | | | |  | | | | | | | END DATE & TIME: | | | | | | |  | | | | |
| **LINE CLEARANCE CHECK:** | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | | **SHIFT** | | | **ATTACHMENT CELL NO.** | | | | **MACHINE NO.** | | | | **PREVIOUS CODE/LOT NO MANUFACTURED** | | | | | **DONE BY**  **(Sign/ Date)** | | | | **VERIFIED BY (Sign/ Date)** |
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| **CHECKS:** | | | | | | | | | | | | | | | **REMARK**  **(Y/N/NA)** | | **DONE BY**  **(Sign/ Date)** | | | **VERIFIED BY (Sign/ Date)** | | |
| 1. Machine cleaning done and Record updated: | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. Input material QC release verification check: | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. No material of previous batch on working table: | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. Raw Material input verification done with BMR: | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. Needle Pull Tester Value:\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. Machine Setting done and Needle Pull check Okay: | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. Status Board Updated: | | | | | | | | | | | | | | |  | |  | | |  | | |
| 1. Needle attachment Die used:   Die Number \_\_\_\_\_\_\_ of \_\_\_\_\_\_\_ mm | | | | | | | | | | | | | | |  | |  | | |  | | |
| **PRODUCTION RECORD:** | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | **SHIFT** | | | **MACHINE NO.** | | | | | | **OPERATOR NAME** | | | | **ATTACHED QUANTITY(Nos)** | | | | **ON LINE REJECTS** | | | **OPERATOR**  **(Sign/ Date)** | |
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| **TOTAL QUANTITY (PCS):** | | | | | |  | | | | | | | | **VERIFIED BY:**  **(Sign & Date)** | | | |  | | | | |
| **NEEDLE AND SUTURE QUANTITY RECONCILIATION:** | | | | | | | | | | | | | | | | | | | | | | |
| **INPUT (Pcs.)** | | | **ISSUED QTY. (A)** | | | | | **PRODUCTION QTY. (B)** | | | | **ON-LINE REJECTION** | | | | **YIELD (%) (C=B/A)** | | | **VERIFIED BY (Sign/ Date)** | | | |
| NEEDLE | | |  | | | | |  | | | |  | | | |  | | |  | | | |
| SUTURE | | |  | | | | |  | | | |  | | | |  | | |  | | | |
| MRN Attached (MRN No.): | | | | | | |  | | | | | | | | | | | | | | | |
| **REMARK:**  **(If Any)** |  | | | | | | | | | | | | | | | | | | | | | |

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| 1. **FIGURE 8 WINDING:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CODE NO.: | | | | |  | | | | | | | | | | | START DATE & TIME: | | | | | | | | | | | |  | | | | | |
| LOT NO.: | | | | |  | | | | | | | | | | | END DATE & TIME: | | | | | | | | | | | |  | | | | | |
| **LINE CLEARANCE CHECK:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | | | | **SHIFT** | | | **WINDING CELL NO.** | | | | **TABLE NO.** | | | | | | | **PREVIOUS CODE/LOT NO MANUFACTURED** | | | | | | | | | | **DONE BY**  **(Sign/ Date)** | | | | | **VERIFIED BY (Sign/ Date)** |
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| **CHECKS:** | | | | | | | | | | | | | | | | | | | | | **REMARK**  **(Y/N/NA)** | | | | | **DONE BY**  **(Sign/ Date)** | | | | | **VERIFIED BY (Sign/ Date)** | | |
| 1. Table cleaning done and Record updated: | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | |  | | |
| 1. Input material QC release & BMR verification check: | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | |  | | |
| 1. No material of previous batch on working table: | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | |  | | |
| 1. Quantity reconciliation at previous work station complete: | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | |  | | |
| **PRODUCTION RECORD:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | **SHIFT** | | | | **MACHINE NO.** | | | | | | | **OPERATOR NAME** | | | | | | | **WOUND QTY.** | | | | | | | | | **ON LINE REJECTS** | | | | **OPERATOR**  **(Sign/Date)** | |
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| **TOTAL QUANTITY (PCS):** | | | | | | | |  | | | | | | | | | | | **VERIFIED BY:**  **(Sign & Date)** | | | | | | | | |  | | | | | |
| **SUTURE WOUND QUANTITY VERIFICATION:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **INPUT QTY. (A)** | | | | | **PRODUCTION QTY. (B)** | | | | | | | | **ON-LINE REJECTION** | | | | | | | | | | **YIELD (%) (C=B/A)** | | | | | | **VERIFIED BY (Sign/ Date)** | | | | |
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| **POST WINDING CHECK:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **ACTIVITY** | | | | | | | | | | | | | **Y/N/NA/Nos.** | | | | | | | | | | | | **CHECKED BY (Sign & Date)** | | | | | | | | |
| ALL BINS LABELLED | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | | | | | |
| TOTAL NUMBER OF BINS | | | | | | | | | | | | |  | | | | | | | | | | | |  | | | | | | | | |
| **REMARK:**  **(If Any)** |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **PRIMARY PACK SEALING ( Nucreal top & Bottom Sealing )** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CODE NO.: | | | | |  | | | | | | | | | | START DATE & TIME: | | | | | | | | | | | |  | | | | | | |
| LOT NO.: | | | | |  | | | | | | | | | | END DATE & TIME: | | | | | | | | | | | |  | | | | | | |
| **LINE CLEARANCE CHECK:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | | **SHIFT** | | | | **MACHINE NO.** | | | | | | | | **PREVIOUS CODE/LOT NO MANUFACTURED** | | | | | | | | | | | | | **DONE BY**  **(Sign/ Date)** | | | | | | **VERIFIED BY (Sign/ Date)** |
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| **CHECKS:** | | | | | | | | | | | | | | | | | | | | | | **REMARK**  **(Y/N/NA)** | | | | **DONE BY**  **(Sign/ Date)** | | | | | **VERIFIED BY (Sign/ Date)** | | |
| 1. Machine cleaning done and Record updated: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. Input material Label verification with BMR done: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. Variable Text verification: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. No material of previous batch on working table: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. Quantity reconciliation at previous work station complete: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. All machine parameters set as per requirement: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. QC released foil components used: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. Machine interlock guarding working Okay: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. Liquid fill unit put ‘ON’ | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| 1. Status Board Updated: | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | |  | | |
| **PRODUCTION RECORD:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **SHIFT** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **MACHINE NUMBER** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **FORMING PRESSURE** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **SEALING TEMP.** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **SEALING PRESSURE** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **SEALING DWELL TIME** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **LIQUID VOLUME SET** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **WEIGHT OF PACK** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **OPERATOR INITIAL** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **CHECKER INITIAL** | | | | | | | | |  | | | | |  | | | | | |  | | | | | | |  | | | | | |  |
| **WOUND QTY (Pcs)(A)** | | | **TOTAL SEAL QTY(6up)(B)** | | | | | | **RECOVERY (6up)(C)** | | | | **REJECTED (Pcs)(D)** | | | | | | **TOTAL SEALED QTY (Pcs)**  **E= (B-C)\*6-D** | | | | | | | | **YIELD (%)**  **= E/A %** | | | | | | **CHECKED BY (Sign/ Date)** |
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| **TUBING FLUID VOLUME CHECK:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **DATE** |  | | | | | | | | |  | | | | | | |  | | | | | | |  | | | | | |  | | | |
| **TIME** |  | | | | | | | | |  | | | | | | |  | | | | | | |  | | | | | |  | | | |
| **WEIGHT OF SIX PACKS**  **(IN GMS)** |  | | | | | | | | |  | | | | | | |  | | | | | | |  | | | | | |  | | | |
| **CHECKER INITIAL** |  | | | | | | | | |  | | | | | | |  | | | | | | |  | | | | | |  | | | |
| **REMARK:**  **(If Any)** |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| 1. **OVERWRAPPING (Medical grade paper & Poly sealing)** | | | | | | | | | | | | | | | |
| CODE NO.: | | | |  | | | | START DATE & TIME: | | | | |  | | |
| LOT NO.: | | | |  | | | | END DATE & TIME: | | | | |  | | |
| **LINE CLEARANCE CHECK:** | | | | | | | | | | | | | | | |
| **DATE** | | **SHIFT** | | | | **MACHINE NO.** | **PREVIOUS CODE/LOT NO MANUFACTURED** | | | | | | **DONE BY**  **(Sign/ Date)** | | **VERIFIED BY (Sign/ Date)** |
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| **CHECKS:** | | | | | | | | | | | **REMARK**  **(Y/N/NA)** | **DONE BY**  **(Sign/ Date)** | | **VERIFIED BY (Sign/ Date)** | |
| 1. Machine cleaning done and Record updated: | | | | | | | | | | |  |  | |  | |
| 1. Input material Label verification with BMR done: | | | | | | | | | | |  |  | |  | |
| 1. Primary sealed pack container released by IPQC: | | | | | | | | | | |  |  | |  | |
| 1. No material of previous batch on working table: | | | | | | | | | | |  |  | |  | |
| 1. Quantity reconciliation at previous work station complete: | | | | | | | | | | |  |  | |  | |
| 1. All machine parameters set as per requirement: | | | | | | | | | | |  |  | |  | |
| 1. QC released foil components used: | | | | | | | | | | |  |  | |  | |
| 1. Machine interlock guarding working Okay: | | | | | | | | | | |  |  | |  | |
| 1. Status Board Updated: | | | | | | | | | | |  |  | |  | |
| **PRODUCTION RECORD:** | | | | | | | | | | | | | | | |
| **DATE** | | | | |  | |  | | |  | | |  | |  |
| **SHIFT** | | | | |  | |  | | |  | | |  | |  |
| **MACHINE NUMBER** | | | | |  | |  | | |  | | |  | |  |
| **SEALING TEMP.** | | | | |  | |  | | |  | | |  | |  |
| **SEALING PRESSURE** | | | | |  | |  | | |  | | |  | |  |
| **SEALING DWELL TIME** | | | | |  | |  | | |  | | |  | |  |
| **OPERATOR INITIAL** | | | | |  | |  | | |  | | |  | |  |
| **CHECKER INITIAL** | | | | |  | |  | | |  | | |  | |  |
| **WOUND QTY(A)** | | | **TOTAL SEAL QTY(B)** | | **RECOVERY (C)** | | **REJECTED (Pcs)(D)** | | **TOTAL SEALED QTY (Pcs)**  **E= (B-C)-D** | | | | **YIELD (%)**  **= E/A %** | | **CHECKED BY (Sign/ Date)** |
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| **REMARK:**  **(If Any)** |  | | | | | | | | | | | | | | |

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| 1. **CARTON PACKING:** | | | | | | | | | | | | | | | | | | | | | |
| CODE NO.: | | |  | | | | | | | START DATE & TIME: | | | | | |  | | | | | |
| LOT NO.: | | |  | | | | | | | END DATE & TIME: | | | | | |  | | | | | |
| **LINE CLEARANCE CHECK:** | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | | **SHIFT** | | | | **TABLE NO.** | | | **PREVIOUS CODE/LOT NO MANUFACTURED** | | | | | | | **DONE BY**  **(Sign/ Date)** | | | | | **VERIFIED BY (Sign/ Date)** |
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| **CHECKS:** | | | | | | | | | | | | **REMARK**  **(Y/N/NA)** | | | **DONE BY**  **(Sign/ Date)** | | | | **VERIFIED BY (Sign/ Date)** | | |
| 1. Table cleaning done and Record updated: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. Input material Label verification with BMR done: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. No material of previous batch on working table: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. Quantity reconciliation at previous work station complete: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. IFU attached: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. QC released overwrap trays available: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. QC released Printed Carton available for packing: | | | | | | | | | | | |  | | |  | | | |  | | |
| 1. Status Board Updated: | | | | | | | | | | | |  | | |  | | | |  | | |
| **PRODUCTION RECORD:** | | | | | | | | | | | | | | | | | | | | | |
| **DATE** | **SHIFT** | | **TABLE NO.** | | | | **OPERATOR NAME** | | | | **PACKED QTY. (CARTON)** | | | | | **REJECTS** | | | | **OPERATOR**  **(Sign/Date)** | |
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| **TOTAL PACKED QUANTITY (CARTONS):** | | | | |  | | | | | | **VERIFIED BY:**  **(Sign & Date)** | | | | |  | | | | | |
| **QUANTITY RECONCILIATION-SUTURE FOIL PACKS:** | | | | | | | | | | | | | | | | | | | | | |
| **INPUT QTY. (Pcs) (A)** | | | **TOTAL QTY. PACKED (Pcs) (B)** | | | | | **QTY. REJECTED (Pcs) (C)** | | | | | | **YIELD (%)**  **D=B/A** | | | **CHECKED BY (Sign/ Date)** | | | | |
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| **QUANTITY RECONCILIATION CARTONS:** | | | | | | | | | | | | | | | | | | | | | |
| **INPUT QTY. (Pcs)** | | | | **TOTAL QUANTITY PACKED (Pcs)** | | | | **TOTAL REJECTION (Pcs)** | | | | | **EXTRA CARTONS** | | | | | **CHECKED BY (Sign & Date)** | | | |
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| **REMARK:**  **(If Any)** |  | | | | | | | | | | | | | | | | | | | | |

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| 1. **CARTON POLY WRAP:** | | | | | | | | | | | | | | | | | | |
| CODE NO.: | | |  | | | | | | START DATE & TIME: | | | | |  | | | | |
| LOT NO.: | | |  | | | | | | END DATE & TIME: | | | | |  | | | | |
| **LINE CLEARANCE CHECK:** | | | | | | | | | | | | | | | | | | |
| **DATE** | | **SHIFT** | | | **MACHINE NO.** | | | **PREVIOUS CODE/LOT NO PACKS** | | | | | | **DONE BY**  **(Sign/ Date)** | | | | **VERIFIED BY (Sign/ Date)** |
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| **CHECKS:** | | | | | | | | | | | **REMARK**  **(Y/N/NA)** | | | **DONE BY**  **(Sign/ Date)** | | | | **VERIFIED BY (Sign/ Date)** |
| 1. Machine cleaning done and Record updated: | | | | | | | | | | |  | | |  | | | |  |
| 1. Input material Label verification with BMR done: | | | | | | | | | | |  | | |  | | | |  |
| 1. No material of previous batch on working table: | | | | | | | | | | |  | | |  | | | |  |
| 1. Quantity reconciliation at previous work station complete: | | | | | | | | | | |  | | |  | | | |  |
| 1. Status Board Updated: | | | | | | | | | | |  | | |  | | | |  |
| 1. Average weight of 10 cartons:   (Allowed weight = average ± 2 gm) | | | | | | | | | | | **AVERAGE WEIGHT (gm)** | | | | **CHECKED BY (Sign/Date)** | | | |
|  | | | |  | | | |
| **QUANTITY RECONCILIATION-SUTURE FOIL PACKS:** | | | | | | | | | | | | | | | | | | |
| **INPUT QTY. (Pcs) (A)** | | **TOTAL QTY. PACKED (Pcs) (B)** | | | | **QTY. REJECTED (Pcs) (C)** | | | | **QA SAMPLES (D)** | | | **YIELD (%)**  **F=B/(A-D)** | | | | **CHECKED BY (Sign/ Date)** | |
|  | |  | | | |  | | | |  | | |  | | | |  | |
| **QUANTITY RECONCILIATION CARTONS:** | | | | | | | | | | | | | | | | | | |
| **INPUT QTY. (Pcs)** | | | | **TOTAL QUANTITY PACKED (Pcs)** | | | **TOTAL REJECTED (Pcs)** | | | | | **QTY. DESTROYED (Pcs)** | | | | **CHECKED BY (Sign & Date)** | | |
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| **REMARK:**  **(If Any)** |  | | | | | | | | | | | | | | | | | |

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| 1. **RADIATION STERILIZATION:** | | | | | | | | | |
| CODE NO.: | | |  | | | START DATE & TIME: | |  | |
| LOT NO.: | | |  | | | END DATE & TIME: | |  | |
| **QUANTITY RECONCILIATION:** | | | | | | | | | |
| **DATE OF DESPATCH** | | **QTY SENT FOR STERILISATION** | | **DATE OF RECEIPT AFTER STERILISATION** | | **QUANTITY RECEIVED AFTER STERILISATION** | **DAMAGE IN TRANSIT**  **(IF ANY)** | | **REMARK** |
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| **CHECKED BY:**  **(Sign/Date)** | | | | | **VERIFIED BY:**  **(Sign/Date)** | | | | |
| **REMARK:**  **(If Any)** |  | | | | | | | | |

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| 1. **FINAL RECONCILIATION AND TRANSFER:** | | | | | |
| **DATE** | **PRODUCTION TRANSFER NOTE NUMBER** | **FG RELEASE QTY.** | **CONTROL SAMPLE** | **SAMPLE WITHDRAWN BY (Sign/Date)** | **CHECKED BY (Sign/Date)** |
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| 1. **POST PACKING CHECK:** | | | | | |
| **OVERALL SUTURE YIELD:** | | | | | |
| **SUTURE INPUT QTY.** | | **PACKED QUANTITY** | **QA SAMPLE** | **OVERALL YIELD (%)** | **CHECKED BY (Sign/Date)** |
|  | |  |  |  |  |
| **REMARK:**  **(If Any)** |  | | | | |

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| --- |
| 1. **WHETHER YIELD SATISFACTORY: YES / NO** |
| **If NO Reason:** |
| 1. **WHETHER ANY QUALITY ISSUE: YES / NO** |
| **If YES Reason:** |
| 1. **NCR/CAPA/OOS NO. AND DESCRIPTION:** |

|  |  |  |
| --- | --- | --- |
| **BMR REVIEWED BY** | | |
|  |  |  |
| **PRODUCTION**  **(Competent Technical Staff)** | **QC**  **(Competent Technical Staff)** | **BATCH RELEASE BY**  **(Quality Assurance)** |