PROTOMATIC

Management Review for 2022

Meeting Certification

This certifies that the Management Review was completed on Jan. 17th, 2023. All of the following items on the agenda were covered. Due to proprietary information, Protomatic does not share these records and they are not available for public review. These are some of the basic areas covered - numbering system is per Protomatic QMS (unless noted):

- X Reviewed of Quality Policy (5.3)- Reference Quality Manual
- X Reviewed of Quality Manual (5.5.2)-Revision Level: P6
- X Reviewed Analysis/Needs Report(s) (5.6.3)
- X Reviewed of Internal Audit Results (8.2.2, 8.4)
- X Reviewed Results of ISO Audit(s) (5.6.2a)
- X Reviewed 2022 Goals vs. Actual, Setting of Goals for 2023 (5.4.1)
- X Reviewed Corrective/Preventive Actions (5.6.2d)
- X Reviewed Training Status (Matrix and Program Health) (6.2.2)
- X Reviewed Infrastructure: Information Tech and Communication Report (6.3)
- X Reviewed Suitable Work Environment (Building & Safety) (6.3, 6.4)
- X Reviewed HR (Attendance, Tardiness and Performance Review Status) (6.4)
- X Reviewed Preventive Maintenance (PRC0902) (7.1.2)
- X Reviewed Risk Assessment (Report on PFEMA, Control Plans, etc.) (7.2.1)
- X Reviewed Purchasing (Approved Vendor List, Vendor Status, T&C) (7.4.2, 7.4.3)
- X Reviewed Process Validation (Ball Bar Report) (7.5.2)
- X Reviewed Customer Property (7.5.4)
- X Reviewed Calibration Report (7.6)
- X Reviewed NCMR- Causes/ Items per month (8.2.3, 8.4)
- X Reviewed Supplier On-Time Delivery (8.2.2, 8.4)
- X Reviewed Scrap Trends Report/month (8.2.3, 8.4)
- X Reviewed Customer On-Time Delivery (Product) /month (8.2.3, 8.4)
- X Reviewed Customer Satisfaction (Parts Accepted) (8.2.3)
- X Reviewed Customer Satisfaction Survey (8.2.3)
- X Reviewed Advisory Notice(s) (FDA 8.5.1)

  Regulatory Compliance Statement: As related to "Medical Device Reporting" in FDA 21CFR Part 820 & 803. Protomatic is typically not the manufacture of record for the complete medical device. Protomatic does not hold the product FDA License, PMA, 510K or a "listed Class 1 device". Therefore Protomatic services do not apply to FDA 21 CFR Parts 820 & 803. Protomatic upon a potential FDA recall will notify the customer and support FDA inspection with the customer.
- X Reviewed Continual Improvement for 2022 (8.5.1)
- X Strategic Planning (AS9100D, 5.1.1.b and 9.3.1)
- X Cyber security Review per SP800-171

On this date, we certified that Annual Management Review was conducted and accepted.

Accepted on: 01/17/2023

Operations Manager: _____

Quality Manager (Management Rep.): Alan Taylor