Quality Objectives

As at 27/10/2025 BN.

POLICY	OBJECTIVE	INDICATOR	Goal	Measurement Tool	Report 20.05.2020	20.05.2020 Incorrect date 26.05.22	15 April 2024
Ongoing Certification & Implementing Good Manufacturing & Distribution Practices	Define an annual Quality Audit schedule programme	Internal Audits	Meet Internal Audit findings plans and deadlines by monitoring the Google sheet register	YES / NO Certification retained	Yes LRQA certification in progress	**# Planned for June 2022** **None Completed as it is only implemented as of May 2022.**	Stage 1 JC Auditors done 7 March 2024 Stage 2 - 14-15 March 2024 Stage 2 JC Audit done 8 April 2025 Superseded any Internal audits - programme to be initiated after stage 2
Compliance with regulations	Ensure compliance to Regulator requirements	Licence & ISO13485 certification	Maintain ISO13485 certification and medical device Licence by maintaining conformity assessment body audit requirements with the audit schedule (programme) in the google sheet register	YES / NO audit audit schedule (programme) achieved	YES	**Date of Issue: 27 November 2017.** **Planned Renewal Application for August 2022.** **Planned ISO 13485 Stage 1 for Q3.**	Licence renewed March 2024 April 2025

Ability to consistently provide products and services that meet requirements	Collect Customer feedback as input to management review	Customer Feedback	Satisfactory Customer Feedback at management review and facility monthly management meetings any actions to follow the IMPROVEMENT **Action plan site**	YES / No Customer Feedback reports satisfactory to management and products and services meet requirements	YES Customer survey to be actioned August	**Only positive feedback to date. Refer to Notes above. Decided no surveys**	Refer positive feedback
Determining the risks and opportunities to achieve its objectives	Perform Risk approach to all processes and procedures	Processes and Procedures Quality Risk Assessment	Risks and opportunities are an input to management review on the topic of recommendations for Improvement where actions follow IMPROVEMENT **Action plan site**	YES / NO Internal Audit findings and effectiveness report back at management review acceptable	YES no new Risks determined and improvement reported in above minutes	**the next meeting.**	No new risks identified as Stage 1 corrective actions focussed
Establishing processes and procedures	Address change and improvement requirements at management review post Data Analysis of	Change Management and Improvement processes	Meet process action plans and deadlines as per **Change Contro**l and monitor through the google sheet register	YES / NO action plans for improvement or correctives actions achieved	YES - new premises and mask equipment impacts to be determined and actions to be followed	**None to date.**	None to date
Following good business ethics and practices	Comply to Dept of Labour and OSH Act requirements	Company compliance	Satisfactory Feedback at management review and covered in monthly management meetings with any actions to follow the IMPROVEMENT **Action plan site**	YES / NO acceptable compliance achieved and YES / NO action plans achieved	YES no reported incidents	**No Nonconformance.**	No incidents recorded

Ensuring that employees are aware and trained	Maintain a Competence and Training Matrix	Competence and Training Matrix	Training Matrix used to monitor and effectively covered in management review input as monitoring and measurement of training process	YES / NO training effectiveness achieved	YES refer data analysis report	- **QMS implementation Awareness Training – 12 April 2025**	- **QMS implementation Awareness Training – 12.02.2025**