

Policy No.	Process Owner	Effective Date
SEPL/QPE/01	Top Management	05/07/2025

Purpose	To establish and communicate the organization's intentions and direction to meet ISO 13485:2016, ISO 15378:2017, Indian MDR 2017 and MDSAP (Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW/PDMA and US FDA), IATF 16949:2016, ISO 9001:2015, RBA, GSV, VDA 6.3, SA 8000, customer, applicable statutory and regulatory requirements. This allows for establishment of the quality objectives and continual improvement.
Scope	This policy is applicable to all plants at Shaily India and at Shaily Innovations (UK). Note: Plants are certified to applicable standards.

Shaily is committed to designing, developing, and manufacturing products adhering to the highest standards of quality and applicable regulatory compliances in an efficient and productive manufacturing environment, that promotes continuous improvement and enhances the effectiveness of our quality management system in an endeavor to provide competitive plastics solutions.

Revision History:

Sr.no.	Revision No.	Revision Date	Revision Details
1	R0	21/02/2022	Quality policy is reviewed and updated in controlled format. The document ID is changed from SEPL-QPE Version 3.0 to SEPL/QPE/01, Revision 0.
2	R1	26/03/2024	In purpose reference of MDR 2017 and all applicable 21 CFR parts are added, and EU 2017/745 is removed. In scope Shaily UK is added. In policy statement design and development mentioned.
3	R2	03/07/2025	➤ MDSAP countries list updated. ➤ Shaily UK is renamed to Shaily Innovations.

Prepared By		Approved By		Revision Date
Name:	Jitesh Darji	Signature	Amit Sanghvi	03/07/2025
Date:	03/07/2025	Signature	03/07/2025	Revision No.
				R2