## **Section Matrix**

Remark: ● Main ○ Support	MD	QMR	HR & GA	Sale	Purchase	Delivery	Warehouse	Planning	Production	PSD	Quality	Engineering	PD Engineer	C&D	П	S & E
4 Context of the organization							>		<u> </u>			Ш	Ь			
4.1 Understanding the organizations & its context	•	•														
4.2 Understanding the needs & expectation of interested parties	•	•														<u> </u>
<ul><li>4.3 Determining the scope of the QMS</li><li>4.3.1 Determining the scope of the QMS - Supplemental</li></ul>	0	•														ļ
<ul><li>4.3.1 Determining the scope of the QMS - Supplemental</li><li>4.3.2 Customer specific requirement</li></ul>	0				<b></b>	<u> </u>										<u> </u>
4.4 Quality Management System & Its Processes	0	•														<b>-</b>
4.1.1.1 Conformance of products & services				0	•	0	0	0	•	0	•	0	0	0		<u></u>
4.1.1.2 Product safety				0	0				0		0	•	0			
<ul><li>Leadership</li><li>Leadership &amp; Commitment</li></ul>	•															
5.1 Leadership & Commitment 5.1.1 General	-		<u> </u>			<u> </u>										<b>-</b>
5.1.1.1 Corporate responsibility	•															<b></b>
5.1.1.2 Process effectiveness & efficiency	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5.1.1.3 Process owner	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5.1.2 Customers Focus											•					<u> </u>
<ul><li>5.2 Policy</li><li>5.2.1 Establishing the Quality policy</li></ul>	•															ļ
5.2.2 Communicating the Quality policy	<b> </b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5.3 Organizational roles, responsibilities & authorities	•	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5.3.1 Organizational roles, responsibilities & authorities - Supplemental	•			•							•					
5.3.2 Responsibility & authority for product requirements & corrective action									•		•					
6 Planning																
6.1 Action to address risks & opportunities 6.1.2.1 Risk Analysis	0	0	0	0	0	•	0	0	•	0	•	0	0	•	•	0
6.1.2.2 Preventive Action		0	0	0	0	0	0	0	•	0	•	0	0	0	0	0
6.1.2.3 Contingency plans		0	0	0	0	0	0	0	0	0	•	0	0	0	0	0
6.2 Quality objective & planning to achieve them		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
6.2.2.1 Quality objective & planning to achieve them - Supplemental		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
7 Support																
7.1 Resources 7.1.1 General																ļ
7.1.2 People			•													<b></b>
7.1.3 Infrastructure			•							•					•	•
7.1.3.1 Plant, facility & equipment planning					0			0	0	•	0	0	0			<b></b>
7.1.4 Environment for the operation of process							0		0	0	0					•
7.1.4.1 Environment for the operation of process - Supplemental							•		•	•	•					<b></b>
7.1.5 Monitoring & measuring resources 7.1.5.1 General											•					ļ
7.1.5.1.1 Measurement System Analysis						<u> </u>										<b></b>
7.1.5.2 Measurement traceability										•						
7.1.5.2.1 Calibration / Verification Record										•						
7.1.5.3 Laboratory requirement										•						
7.1.5.3.1 Internal laboratory										•						ļ
7.1.5.3.2 External laboratory 7.1.6 Organizational Knowledge			•			<u> </u>				•						<b></b>
7.2 Competence		•	•	•	•	•	•	•	•	•	•	•	•	•	•	-
7.2.1 Competence - Supplemental									•		•					
7.2.2 Competence – on the job training									•		•					
7.2.3 Internal auditor competency		•				ļ										<b></b>
<ul><li>7.2.4 Second-party auditor competency</li><li>7.3 Awareness</li></ul>			•		•											<b></b>
7.3.1 Awareness - Supplemental						<u> </u>			-		•					<b></b>
7.3.2 Employee motivation & empowerment			•													
7.4 Communication		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7.5 Document Information		•														
7.5.1 General		•														ļ
7.5.1.1 QMS Documentation 7.5.2 Creating & Updating		•	•	•	•	•	•	•	•	•	•	•	•	•	•	<b> </b>
7.5.3 Control of document information		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
7.5.3.2.1 Record retention		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
7.5.3.2.2 Engineering Specifications																
8 Operation																ļ
8.1 Operation Planning & Control  8.1.1 Operation Planning & Control - Supplemental						0			•		•	•				<b></b>
8.1.2 Confidentiality				0	0	0	0	0	0	0			0			<b></b>
8.2 Requirements for Products & Service											•	•				
8.2.1 Customer communication				•	0	0					•	•				<b></b>
8.2.1.1 Customer communication - Supplemental				•	0	0					•	•				<u> </u>
8.2.2 Determine of requirements related to the products & services			<u> </u>	•	0	0		ļ				•				<u> </u>
<ul><li>8.2.2.1 Determine of requirements related to the products &amp; services - Supplemental</li><li>8.2.3 Review of requirements related to the products &amp; services</li></ul>			<u> </u>	•	<u> </u>	<u> </u>		<b></b>		<u> </u>	<u> </u>	•	<u></u>			<b></b>
8.2.3.1.1 Review of requirements related to the products & services  8.2.3.1.1 Review of requirements related to the products & services - Supplemental						<b></b>		<b></b>								<del> </del>
8.2.3.1.2 Customer-design special characteristic			<b></b>	<b></b>		<b></b>		<b></b>			0	•				<b> </b>
8.2.3.1.3 Organization manufacturing feasibility			<u></u>									•				
8.2.4 Changes of requirements for products and services												•				
8.3.3.2 Manufacturing design input			ļ		<u> </u>			<u> </u>				•				<u> </u>
<ul><li>8.3.3.3 Special Characteristics</li><li>8.3.4 Design and Development Controls</li></ul>			<u> </u>	<u> </u>	<u> </u>	<u> </u>		<u> </u>	<b>.</b>	<u> </u>	<u> </u>	•	<u> </u>			<b> </b>
8.3.4.1 Monitoring			l	<u> </u>	<b></b>	<b></b>		ļ		<u> </u>	<u> </u>	•	<b></b>			<b> </b>
			ı	I	I	ļ	<u> </u>	ļ	<b>.</b>	ļ	ļ	L	ı	1	l	<b></b>
											0	•				1
8.3.4.2 Design & Development Validation 8.3.4.3 Prototype programme											0	•				

	<u>:</u> ● Main ○ Support																
			~	₽ S		se	Ę.	use	Bu	tion		£	ring	inee			ш
		MD	QMR	∞ర	Sale	Purchase	Delivery	Warehouse	Planning	Production	PSD	Quality	Engineering	PD Enginee	C&D	⊨	∞ ∽
				壬		Pu		Wa		Pro		0	Eng	PD			U)
8.3.5	Development and design outputs											0	•				
8.3.5.2	Manufacturing process design output									0	0	0	•				
	Development and Design changes												•				
	Development and Design changes - Supplemental											0	•				
L	Control of External Provider Processes, Products & Services					•											
8.4.1.1	Control of External Provider Processes, Products & Services - Supplemental					•											
L	Supplier selection process					•											
8.4.1.3	Customer-directed sources					•											
8.4.2	Type & extent of control					•											<u> </u>
8.4.2.1	Type & extent of control - Supplemental					•											ļ
L	Statutory & regulatory requirements					•											<u> </u>
L	Supplier QMS development					•											<u> </u>
L	Supplier monitoring					•											<u> </u>
	Second party audits					•											<u> </u>
<b></b>	Supplier development					•											<u> </u>
L	Information for external providers					•											<u> </u>
	Information for external providers - Supplemental					•			ļ				ļ				<b> </b>
	Production and Service Provision					•											<b></b>
	Control Plan												•				<b></b>
L	Standardised work-operator instruction and visual standard									•		•	ļ				<b> </b>
<b>L</b>	Verification of job set-up									•							<b></b>
L	Verification after shutdown	ļ		ļ	<b> </b>	<b>.</b>	<u> </u>		<b>.</b>	•							<b></b>
<b></b>	Total productive maintenance	<u></u>		ļ	<b> </b>	<b></b>	<u> </u>		<b>.</b>		•						<b></b>
	Management of production tooling and manufacturing, test, inspection tooling and equip	ment		<b>.</b>	<b> </b>	<b></b>	<b>.</b>			•	•			<b></b>	ļ		<b> </b>
L	Production scheduling	ļ		<b>.</b>	<b> </b>	<b></b>	<b></b>	•	•					<b></b>			<b> </b>
	Identification and traceability	ļ			<b> </b>	<b></b>	<b></b>		<b></b>		•	•		<b></b>			<b> </b>
	Identification and traceability - supplemental Property belonging to customers or external providers	ļ		<b>.</b>	<b> </b>	ļ	<b></b>		<b>.</b>	0	0	_		<b>_</b>			<b> </b>
																	<b></b>
	Preservation									0		0					<b></b>
	Preservation - supplemental									0		•					<b></b>
	Post delivery activities																ļ
	Feedback of information from service																ļ
l	Service agreement with customer  Control of changes									_							<b> </b>
L	Control of changes - supplemental																<b></b>
L	Temporary chages of process control																<b>-</b>
L	Release of product and service																<b> </b>
L	Release of product and service - supplemental						<b></b>			0		•	<b></b>				<b>-</b>
8.6.2	Layout inspection and functional testing									0		•					<del> </del>
<b></b>	Appearance									0		•					<del> </del>
L	Verification and acceptance of conforming of externally provided product and service					0						•					<del> </del>
8.6.5	Statutory and regulatory conformity					0						•					<del> </del>
L	Acceptance criteria						<b></b>					•	<b></b>				<del> </del>
L	Control of nonconforming output									•		•					<del> </del>
L	Customer authorization for concession											•	<b></b>				<b>-</b>
<b></b>	Control of nonconforming product customer-specified process									•		•					<b> </b>
L	Control of suspect product									•		0					<b> </b>
L	Control of reworked product									•		•					<b> </b>
	Control of repaired product									•		•					<b> </b>
<b>k</b>	Customer notification											•					<b> </b>
<b>L</b>	Nonconforming product disposition									•		•					<b> </b>
9	Performance Evaluation																<b> </b>
9.1	Monitoring, Measurement, Analysis and Evaluation									•		•	•				<b></b>
L	Monitoring and measurement of manufacturing process)									•		•	•				<b> </b>
	Identification of statistical tools	<b>†</b>		<b></b>	<b> </b>	l	<b> </b>		<b>1</b>	0	l	•	•	1			<b> </b>
<b></b>	Application of statistical concepts									0		•					<u> </u>
	Customer Satisfaction				•												
	Customer Satisfaction - supplemental				•												<u> </u>
9.1.3	Anaysis and evaluation		0	<b></b>	0	0	<u> </u>		0	0		0	0				<u> </u>
9.1.3.1	Prioritization						<u> </u>					•					
9.2	Internal Audit		•				<u> </u>										
	Internal audit plan		•														
h	Quality management system audit		•														
l	Manufacturing process audit		0									•					
	Product audit		0									•					
	Management review	•	•														ļ
	Management review - supplemental		•														<u> </u>
	Management review input		•				ļ		ļ				 				<u> </u>
	Management review input - supplemental		•		<b> </b>	<u> </u>	<b></b>		<u> </u>	<u> </u>				ļ			<u> </u>
	Management review output		•		ļ		ļ							<u> </u>			<u> </u>
	Management review output - supplemental		•														ļ
10	Improvement																
	General		0		<b></b>	<u> </u>	<u> </u>		<u> </u>	•		•		•			<b></b>
	Nonconformity and corrective action		0	0	0	0	0	0	0	•	0	•	0	•	0	0	0
	Problem solving				ļ	<u> </u>	ļ			•		•	•	•			<u> </u>
	Error proofing				<b> </b>	<u> </u>	<b></b>		<u> </u>	•		0	•	•	ļ		<b></b>
	Warranty management systems			ļ	<b></b>	<u> </u>	<u> </u>		<u> </u>	<u> </u>		•		ļ			<b></b>
	Nonconforming complaints and field test analysis	<b> </b>		<b> </b>	<b> </b>	<b> </b>	<b> </b>		<b> </b>		ļ	•	 		ļ		<b></b>
10.3	Continual improvement	<u> </u>		<b>.</b>	<b> </b>	<u> </u>	ļ		<u> </u>	•	ļ	0		•	ļ		<b></b>
			_	1		ı	I	ı	I	•	I	0	ı		1		Ī
	Continual improvement - supplemental				ļ	ļ		<b></b>	<del> </del>	<b></b>			<b></b>				<b></b>