

	KANNAN TOOLS AND DIES ISO 13485:2016 Quality Management System	Doc. No: MDQMS-QM-01 Issue No: 01
Doc. Title:	Quality Manual	

1.1 Scope of Application / Registration

Name	Address	Scope
Kannan Tools and Dies	Site No:62 , SF No: 224/2 , 224/4, Sri Subha Ganesh Industrial Estate, Kuppepalayam , Coimbatore - 641107, Tamil Nadu INDIA.	Manufacturing And Supply of Machined Components For Medical Application

1.3 Exclusion & Non-Applicability:

Due to the nature of the product and the process, KANNAN TOOLS AND DIES does not perform the following activities defined in ISO 13485. Thus, they are non-applicable and excluded in this quality system.

ISO 13485 Clause No	Justification for Exclusion and Non Applicability
7.3 Design and development (7.3.1 to 7.3.10)	Not Applicable and excluded . KTD is not involved in any design activity. At present the parts and components are manufactured based on the customer Drawing/specifications/requirements. As such, the non-applicability of this requirement does not affect our ability or responsibility to provide the product meeting customer requirements and applicable regulatory requirements
7.5.2 Cleanliness of product	The products that are manufactured by the Kannan Tools and Dies are non-sterile and without cleaning condition and it is not a requirement of customer/ contractual requirements. As such, the exclusion of this requirement does not affect our ability or responsibility to provide the product meeting customer requirements and applicable regulatory requirements
Installation of medical devices – Section 7.5.3	The products that are manufactured by the Kannan Tools and Dies are not installed. Those are installed by the customer /physicians at their end. Hence this clause is not applicable and excluded from the scope.
Servicing of medical devices – Section 7.5.4	The products that are manufactured by the Kannan Tools and Dies are not under service. These are non-



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	serviceable products. There is no contractual requirements from the customer for the product service. Hence this clause is not applicable and excluded from the scope
Particular requirements for sterile medical devices – Section 7.5.5	The products that are manufactured by the Kannan Tools and Dies are delivered as non sterile condition. There is no regulatory and/or contractual requirements for sterilization of the implants. Hence this clause is not applicable and excluded from the scope
Particular requirements for Validation of processes for sterilization and sterile barrier Systems – Section 7.5.7	The products that are manufactured by the Kannan Tools and Dies are delivered as non sterile condition. There is no regulatory and/or contractual requirements for sterilization of the implants. Hence this clause is not applicable and excluded from the scope