

Saimax Healthcare & Surgicals

Doc. No.	Rev.	Review
SH/F-01	00	31.12.2025

List of Records for Loan License MD-4

S. No.	Check List	Status
1.	Cover Letter	Prepare By us
2.	Constitution of firm	
3.	The Establishment /Site ownership /Tenacy Agreement	
4.	Copy of Certificate supporting quality management system (ISO: 13485)	
5.	Plant Master file	From Actual Manufacturer
6.	Device Master file	Prepare By us
7.	Performance Evaluation of the device	Prepare By us
8.	Undertaking Regarding 5 th Schedule	Prepare By us
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23.	Packing Material Specification & Protocol	
24.	Packing Validation Report	
25.	Plant Master File	
26.	Post Market Surveillance Record	
27.	Preventive Maintenance Checklist	
28.	Production Register	
29.	QMS	
30.	Raw Material Inspection Report	
31.	Raw Material Reports Record	
32.	Raw Material Specification & Protocol	
33.	Raw Material Stock Register	
34.	Raw Material Test Report	
35.	Return Goods Record + Investigation Record	

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36.	Risk Management File	
37.	Standard Operating Procedure	
38.	Temperature & Humidity Record	
39.	Training Records, Training Calendar	
40.	Vendor Approval records	
41.	Water Test Report	
42.	Work Instructions	
43.	Self-Inspection Record	
44.	Calibration Record	
45.	List of Machine	
46.	Non-conforming Record	
47.	Quality Objective + Quality Policy	
48.	List of SOP	
49.	Pressure & Differential Record	If Required
50.	UV Light Record	
51.	Master List of Documents	
52.	Technical Staff document	
53.	ETO Validation Record	If Required
54.	Clean Room Validation	If Required