Saimax Healthcare & Surgicals		
Doc. No.	**Rev.**	**Review**
SH/F-01	**00**	**31.12.2025**

List of Records for Manufacturing License

S. No.	List of Records	Status
1.	Agreements + Contract Review+ MOU	
2.	Batch Manufacturing Record & Material Requisition Slips	
3.	Biocompatibility	If Required
4.	Breakdown Record	
5.	Cleaning Record of Premises	
6.	Clinical Evaluation Report	
7.	Competency Matrix + Responsibility	
8.	Control Sample Record	
9.	Design Verification & Validation File	
10.	Device Master File	
11.	FG Test Report	
12.	Finished Good Specification & Protocol	
13.	Finished Good Stock Register	
14.	Formats	
15.	Internal Audit Record	
16.	Incoming register	
17.	Label and Instruction for MD for all products	
18.	License File (Fire, Pollution, ISO, MD-3, MD-7)	
19.	List of Machines and equipment	
20.	List of Records	
21.	Management Review Meeting, Memo	
22.	Medical Examination Record	
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	
36.	Risk Management File	
37.	Standard Operating Procedure	

J-997, RIICO Industrial Area Chopanki Bhiwadi Distt.- Alwar Rajasthan-301019
Email: saimaxhealthcare@gmail.com,
Contact: 09716263625, 07023353183

List of Records for Manufacturing License

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