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Products List (Regulatory Solutions)

S.No.		Services Offered
European Union (EU)		
1.		**EC REP Services**
2.		**CE (Regulation (EU) 2017/746 (IVDR)) (Product Description)**
	2.1	Risk class assessment of Device
	2.2	Conformity Assessment Routes
	2.3	Device Master File
	2.4	Site Master File
	2.5	Risk Management Plan
	2.6	General Safety and Performance Requirements (GSPR)
	2.7	Notified Bodies: Product authorization check and coordination
3.		**CE (Regulation (EU) 2017/745 (MDR) (Product Description)**
	3.1	Risk class assessment of Device
	3.2	Conformity Assessment Routes
	3.3	Device Master File
	3.4	Site Master File
	3.5	Risk Management Plan
	3.6	General Safety and Performance Requirements (GSPR)
	3.7	Notified Bodies: Product authorization check and coordination
4.		**Unique Device Identification (UDI) strategy consultation (Product Description)**
	4.1	Basic UDI-DI for product group
	4.2	Matrix for attributing Basic UDI-DI for products
	4.3	Basic UDI-DI creation as per established rules in the regulatory framework
	4.4	UDI-DI and UDI-PI creation as per established rules in the regulatory framework
5.		**Post Market Surveillance System (IVDR) (Product Description)**
	5.1	Post Market Surveillance Plan (SOP)
	5.2	Post Market Performance Follow-up (PMPF) Plan

	5.3	PMPF Study
	5.4	PMPF Clinical Investigation
	5.5	Clinical Investigation Plan
	5.6	PMPF Evaluation Report
	5.7	Performance Evaluation Report (PER)
	5.8	Vigilance System (SOP)
	5.9	Serious Incidents Reports
	5.10	Field Safety Corrective Actions
	5.11	PMS Report (Class A and B devices)
	5.12	Periodic Safety Update Report (PSUR) – (Class C and D devices)
6.		**Post Market Surveillance System (MDR) (Product Description)**
	6.1	Post Market Surveillance Plan (SOP)
	6.2	Post Market Clinical Follow-up (PMCF) Plan
	6.3	PMCF Study
	6.4	PMCF Clinical Investigation
	6.5	Clinical Investigation Plan
	6.6	PMCF Evaluation Report
	6.7	Clinical Evaluation Report (CER)
	6.8	Vigilance System (SOP)
	6.9	Serious Incidents Reports
	6.10	Field Safety Corrective Actions
	6.11	PMS Report (Class I devices)
	6.12	Periodic Safety Update Report (PSUR) – (Class IIa, IIb and III devices)
7.		**EU Registration**
	7.1	EUDAMED Registration
	7.2	Registration of devices with Competent Authorities of the EU member states
8.		**Regulatory Training – (EU) 2017/745 Medical Device Regulation (MDR)**

9.		**Regulatory Training – (EU) 2017/746 Medical Device Regulation (IVDR)**
10.		**Technical File Support (MDR) (Product Description)**
	10.1	Device Description
	10.2	Manufacturer Information
	10.3	Design and Manufacturer
	10.4	General Safety and Performance Requirement
	10.5	Risk-Benefit Analysis and Risk Management
	10.6	Verification and Validation
11.		**Technical File Support (IVDR)**
	11.1	Device Description
	11.2	Manufacturer Information
	11.3	Design and Manufacturer
	11.4	General Safety and Performance Requirement
	11.5	Risk-Benefit Analysis and Risk Management
	11.6	Verification and Validation
12.		**Clinical Evaluation (MDR) – Pre-Market**
	12.1	Clinical Evaluation Plan (CEP)
	12.2	Clinical Evaluation Report (CER)
	12.3	Technical Performance
	12.4	Valid Clinical Association
	12.5	Clinical Performance Report
13.		**Performance Evaluation (IVDR) – Pre-Market**
	13.1	Performance Evaluation Plan
	13.2	Performance Evaluation Report (PER)
	13.3	Analytical Performance Report
	13.4	Scientific Validity Report
	13.5	Clinical Performance Report

14.		**Labelling Compliance**
	14.1	Label texts for medical devices
	14.2	Artworks for medical devices
	14.3	Label texts for IVDs
	14.4	Artworks for IVDs
15.		**Swiss Authorized Representative (CH REP) (Medical Devices Ordinance (MedDO; SR 812.213))**
16.		**Registration of devices with Competent Authorities of Switzerland**
17.		**Labelling Compliance**
	17.1	Label texts for medical devices
	17.2	Artworks for medical devices
	17.3	Label texts for IVDs
	17.4	Artworks for IVDs
18.		**Post Market Process Documentation**
	18.1	Serious Incidents Reports
	18.2	Field Safety Corrective Actions (taken in Switzerland)
	18.3	Summaries of Safety and Clinical Performance (SSCPs)
India		
19.		**Authorized Agent/Distributor Services**
20.		**Marketing/Import permission from Central Drugs Standard Control O0rganization (CDSCO)**
	20.1	Covering Letter (CDSCO format)
	20.2	Power of Attorney authenticated in India by a Magistrate of First Class (Part I of Forth Schedule)
	20.3	NOC from Department of Animal Husbandry, Ministry of Agriculture (India)
	20.4	NOC from Bhabha Atomic Research Centre (BARC), Mumbai (India)
	20.5	Site or Plant Master file as specified in Appendix I of Fourth Schedule of MDR 2017

	20.6	Device Master File for Medical Device or In-Vitro Diagnostic Medical Devices as per Appendix – III of Fourth Schedule of Medical Devices Rules, 2017
	20.7	Correlation Chart with respect to product list mentioned in MD-14 and FSC submitted
21.		**Manufacturing License from Central Drugs Standard Control Organization (CDSCO)**
	21.1	Manufacturing Process Flowchart including process check and report control
	21.2	Process Validation Report
	21.3	Analytical Method Validation Report
	21.3	Material Safety Datasheet
	21.4	Reference Product Characterization
22.		**Registration of device at Indian Council of Medical Research (ICMR)**
23.		**Clinical Validation at the selected medical facilities of Indian Council of Medical Research (ICMR)**
24.		**Labelling Compliance**
	24.1	Label texts for medical devices
	24.2	Artworks for medical devices
	24.3	Label texts for IVDs
	24.4	Advise and prepare India complaint artworks for IVDs
USA		
25.		**FDA Establishment Registration (21 Code of Federal Regulation (CFR) Part 807)**
26.		**Medical Device Listing (21 CFR Part 807)**
27.		**Pre-Market Notification 510 (k)**
28.		**Pre-Market Approval**
29.		**Investigational Device Exemption (IDE)**
30.		**Quality System Regulation (QS regulation)**
31.		**Labeling - (21 CFR Part 801)**
	31.1	Label texts for medical devices
	31.2	Artworks for medical devices

	31.3	Label texts for IVDs
	31.4	Artworks for IVDs
32.		**Medical Device Reporting (21 CFR Part 803)**
33.		**ISO**
	33.1	ISO 9001: Quality Management System
	33.2	ISO 13485: Design and Manufacture of Medical Devices
	33.3	ISO 14971: Medical Device Risk Management
	33.4	ISO 14001: Environmental Management System
	33.5	ISO/IEC 27001: Standard which helps organizations "establish, implement, operate, monitor, review, maintain and continually improve an Information Security Management System
	33.6	ISO 20417: Requirements for the general information that manufacturers have to supply with their medical devices and IVD devices.
	33.7	ISO/TR 20416: Medical devices-post-market surveillance for manufacturers
34.		**Certificate of Free Sales**
	34.1	Documentation and Submission EU
	34.2	Documentation and Submission Switzerland
	34.3	Documentation and Submission India
	34.4	Documentation and Submission Middle Eastern, Southeast Asian and South American Countries

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