



Item	Categories/Industries	Service Names	Service Descriptions
1	Medical	Standards Engineering Consulting	<p>May include one or more or all of the following services:</p> <ul style="list-style-type: none"> <li>● “Critical components” review</li> <li>● Pre-compliance construction review to IEC 60601 series standards (particular and collateral standards)</li> <li>● Marking and labeling review</li> <li>● Coordinate submission and testing with third-party test labs</li> <li>● Prepare documentation for product safety certification submission</li> <li>● CB Scheme guidance</li> <li>● Obtain quotes from third-party test labs for comparison</li> <li>● Risk management file review (RMF) per ISO 14971</li> <li>● Risk analysis and assessment</li> <li>● Integration (design inputs) of standards requirements throughout product development cycle</li> <li>● Recommend design changes to solve non-compliances</li> <li>● Test protocol development</li> </ul>
2	Medical	Conceptual Design Consulting	Conceptual design based on customer’s intended clinical indications, preferred technologies, costs, and other parameters.
3	Medical	USFDA Regulatory Consulting	Class I, II (510k), and III (PMA) regulatory consulting and submission including establishment registration, device listing, and CFG <i>for active and non-active medical devices</i> .
4	Medical	ASEAN Regulatory Consulting	Class A, B, C, and D regulatory consulting and submission including, economic operators search/matching, and CAB search <i>for active and non-active medical devices</i> .
5	Medical	Health Canada Regulatory Consulting (CMDR)	Class I, II, III, and IV regulatory consulting and submission including



			establishment license (MDEL), and MDL <i>for active and non-active medical devices.</i>
6	Medical	Australia Regulatory Consulting (TGA)	Class 1, Class Is, Class Im, Class IIa, Class IIb, Class III regulatory consulting and submission including, economic operators search/matching <i>for active and non-active medical devices.</i>
7	Medical	EU MDR CE marking	Class 1, Class Is, Class Ir, Class Im, Class IIa, Class IIb, Class III regulatory consulting and submission including, economic operators search/matching (AR via Obelis, importer, distributor), and PRRC search/matching <i>for active and non-active medical devices.</i>
8	Medical	UKCA marking	Class 1, Class Is, Class Im, Class IIa, Class IIb, Class III regulatory consulting, device registration, and submission including, economic operators search/matching (importer, distributor), and UKRP search/matching <i>for active and non-active medical devices.</i>
9	Medical	Other markets	On a case-by-case basis.
10	Medical	ISO13485	<ul style="list-style-type: none"> <li>● Development of quality manual and QOPs/SOPs including regulatory requirements based on target markets and scope of activities</li> <li>● Training</li> <li>● Assist with formal audits through certification</li> <li>● Internal audits</li> </ul>
11	Medical	ISO14971	<ul style="list-style-type: none"> <li>● Provide guidance on risk management according to ISO14971</li> </ul>
12	Medical	Person Responsible for Regulatory Compliance (PRRC) - EU MDR Requirement	<ul style="list-style-type: none"> <li>● Provide services as a PRRC to perform its obligations under the EU MDR</li> </ul>
13	Medical	UK Responsible Person (UKRP)	<ul style="list-style-type: none"> <li>● Provide services under the UK MDR 2002 for foreign manufacturers</li> </ul>
14	Medical	Regulatory Strategy Across Markets	<ul style="list-style-type: none"> <li>● Provide regulatory strategy prior to or early design stage to identify</li> </ul>



			regulatory requirements across markets and best regulatory path to cover markets in an efficient and cost effective approach.
15	<b>Cosmetics</b>	GCC (Gulf Coast Countries) Cosmetic Regulatory Consulting	Verification of prohibited and restricted ingredients, identification of specific regulatory steps/processes, review of marketing and advertising materials, assist with regulatory submission, and labeling review
16	<b>Cosmetics</b>	Mexico Cosmetic Regulatory Consulting	Verification of prohibited and restricted ingredients, identification of specific regulatory steps/processes, review of marketing and advertising materials, assist with regulatory submission, and labeling review
17	<b>Cosmetics</b>	EU/UK Cosmetic Regulatory Consulting via Obelis	Verification of prohibited and restricted ingredients, identification of specific regulatory steps/processes, review of marketing and advertising materials, assist with regulatory submission, and labeling review
18	<b>Cosmetics</b>	Japan Cosmetic Regulatory Consulting	Verification of prohibited and restricted ingredients, identification of specific regulatory steps/processes, review of marketing and advertising materials, assist with regulatory submission, and labeling review
19	<b>Cosmetics</b>	ASEAN Cosmetic Regulatory Consulting	Verification of prohibited and restricted ingredients, identification of specific regulatory steps/processes, review of marketing and advertising materials, assist with regulatory submission, and labeling review
20	<b>Cosmetics</b>	Australia Cosmetic Regulatory Consulting	Verification of prohibited and restricted ingredients, identification of specific regulatory steps/processes, review of marketing and advertising materials, assist with regulatory submission, and labeling review
21	<b>Cosmetics</b>	Other markets	On a case-by-case basis.
22	<b>Industrial/Commercial Automation</b>	Machinery Directive Consulting	May include one or more or all of the following services: <ul style="list-style-type: none"> <li>● "Critical components" review</li> <li>● Pre-compliance construction review to applicable standards</li> </ul>





			<ul style="list-style-type: none"> <li>● Marking and labeling review</li> <li>● Coordinate submission and testing with third-party test labs</li> <li>● Prepare documentation for product safety certification submission</li> <li>● Obtain quotes from third-party test labs for comparison</li> <li>● Risk analysis and assessment</li> <li>● Integration (design inputs) of standards requirements throughout product development cycle</li> <li>● Recommend design changes to solve non-compliances</li> <li>● ISO 9001 QMS development</li> <li>● Assist with technical file documents</li> </ul>
23	<b>Industrial/Commercial Automation</b>	Autonomous Guided Vehicles (AGVs) Consulting	<p>May include one or more or all of the following services:</p> <ul style="list-style-type: none"> <li>● "Critical components" review</li> <li>● Precompliance construction review to applicable standards</li> <li>● Marking and labeling review</li> <li>● Coordinate submission and testing with third-party test labs</li> <li>● Prepare documentation for product safety certification submission</li> <li>● Obtain quotes from third-party test labs for comparison</li> <li>● Risk analysis and assessment</li> <li>● Integration (design inputs) of standards requirements throughout product development cycle</li> <li>● Recommend design changes to solve non-compliances</li> <li>● Test protocol development</li> <li>● Single or multi-fleet</li> <li>● ISO 9001 QMS development</li> </ul>
24	<b>Consumer Products</b>	Household Appliances Consulting	May include one or more or all of the following services:



			<ul style="list-style-type: none"> <li>● “Critical components” review</li> <li>● Precompliance construction review to applicable standards</li> <li>● Marking and labeling review</li> <li>● Coordinate submission and testing with third-party test labs</li> <li>● Prepare documentation for product safety certification submission</li> <li>● CB Scheme guidance</li> <li>● Obtain quotes from third-party test labs for comparison</li> <li>● Risk analysis and assessment</li> <li>● Integration (design inputs) of standards requirements throughout product development cycle</li> <li>● Recommend design changes to solve non-compliances</li> <li>● Test protocol development</li> </ul>
25	<b>Consumer Products</b>	ITE Products Consulting	<p>May include one or more or all of the following services:</p> <ul style="list-style-type: none"> <li>● “Critical components” review</li> <li>● Precompliance construction review to applicable standards</li> <li>● Marking and labeling review</li> <li>● Coordinate submission and testing with third-party test labs</li> <li>● Prepare documentation for product safety certification submission</li> <li>● CB Scheme guidance</li> <li>● Obtain quotes from third-party test labs for comparison</li> <li>● Risk analysis and assessment</li> <li>● Integration (design inputs) of standards requirements throughout product development cycle</li> <li>● Recommend design changes to solve non-compliances</li> <li>● Test protocol development</li> </ul>



26	<b>Environmental &amp; Restricted Substances</b>	US Environmental Protection Agency (EPA) Consulting	Identify applicable facility, device or product requirements and assist with implementation and documentation.
27	<b>Environmental &amp; Restricted Substances</b>	RoHS Consulting	Identify applicable device or product requirements and assist with implementation and documentation.
28	<b>Environmental &amp; Restricted Substances</b>	California Prop 65 Consulting	Identify applicable device or product requirements and assist with implementation and documentation.
29	<b>Environmental &amp; Restricted Substances</b>	REACH Consulting	Identify applicable device or product requirements and assist with implementation and documentation.
30	<b>Military</b>	US Military Requirements Consulting	<ul style="list-style-type: none"> <li>● Identify applicable requirements/standards for products or devices for military applications or use</li> <li>● Provide design inputs based on applicable requirements</li> <li>● Assist with certification from obtaining quotes to testing submission</li> </ul>