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INDEPENDANT CONSULTING FOR QUALITY AND REGULATORY AFFAIRS

EXPERTS FOR MEDICAL DEVICES

REFERENCES

❒ OUTSOURCED SERVICES

DATE	POSITION	ACTIVITIES	MEDICAL DEVICES
2013 to Now	QUALITY AND REGULATORY AFFAIRS MANAGER	company which designs and manufactures biological prosthesis. Set up of a quality system according to the requirements ISO 13485, 21 CFR Part 820, and European regulations. Preparation of the certification ISO 13485. Obtention CE mark. Management of ANSM inspections.	Biological prothesis for soft tissue repairs Class III (EU) / II (USA)
2009 to 2018	QUALITY AND REGULATORY AFFAIRS MANAGER	company which designs and manufactures electro-medical devices. Quality system follow-up according to the requirements of the US, Canadian and European regulations. Maintain of the certification ISO 13485 and ISO 9001. CE mark procedures follow-up and international registration procedures (Brazil, Japan, USA, Europe, Canada...).	Electromedical instrument Class IIa (EU) / II (USA) Orthopedics
2010-2012	QUALITY AND REGULATORY AFFAIRS MANAGER	company which designs and manufactures spinal implants and instrumentation. Implementation of a quality system, management of the certification ISO 13485, CE mark procedure follow-up and 510[k] registration	Spinal implants and instruments Class IIb (EU) / II (USA)
2009 - 2012	QUALITY AND REGULATORY AFFAIRS MANAGER	subcontracting company of packaging. Implementation of a quality system according to the requirements of the US and European regulations. Management of the certification ISO 13485 and ISO 9001.	Subcontracting activities of cleaning, labeling and packaging for sterile devices

❒ INTERNAL AUDITS / SUPPLIERS-PROCESS AUDITS

ADEQUAT EXPERTISE auditor is qualified and registered as IRCA (International Register of Certificated Auditor), Registration number 30827. Main audited standards are: ISO 13485 / US cGMP

DATE	ACTIVITY	COUNTRY	STATE	NB of days
2003	Orthopedics	France	94	1.5
2004	Orthopedics	FRANCE	86	1.5
2005	sterile packaging	FRANCE	13	2
2005	Orthopedics	FRANCE	17	2
2005	Orthopedics	FRANCE	17	1.5
2005	Orthopedics	FRANCE	17	2
2005	Orthopedics	FRANCE	69	1
2006	Orthopedics	FRANCE	17	1
2006	Orthopedics	FRANCE	17	2
2006	sterile packaging	FRANCE	13	2

Adequat EXPERTISE

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2007	Orthopedics	USA	USA	4
2008	Orthopedics	FRANCE	59	1
2008	Orthopedics	FRANCE	69	1.5
2008	Orthopedics	FRANCE	13	3.5
2009	Orthopedics	FRANCE	17	1.5
2009	sterile packaging	FRANCE	17	1.5
janv-10	IVD MD	FRANCE	33	1.5
févr-10	Electronic parts	SINGAPORE	SING	3.5
févr-10	sterilisation	FRANCE	60	1.5
févr-10	sterile packaging	FRANCE	17	1
avr-10	Orthopedics	FRANCE	94	2
juin-10	IVD MD	FRANCE	33	1.5
sept-10	Orthopedics	FRANCE	85	1
oct-10	Cardiac surgery	SUISSE	SUISSE	2
oct-10	Cardiac surgery	SUISSE	SUISSE	2.5
nov-10	Orthopedics	France	92	1
déc-10	Orthopedics	France	94	2
juil-11	IVD MD	FRANCE	33	3
oct-11	IVD MD	INDE	Mumbay	3
sept-11	Orthopedics	FRANCE	59	1
mars-12	Orthopedics	FRANCE	76	1
avr-12	Vascular surgery	FRANCE	59	1
oct-12	Orthopedics	FRANCE	69	2
nov-12	Electronic parts	SINGAPORE	SING	4
mai-13	Orthopedics	DK	DK	3
juin-13	ophtalmic surgery	FRANCE	22	2
sept-13	sterile Packaging	FRANCE	42	2
oct-13	Orthopedics	FRANCE	89	4
oct-13	Orthopedics	TUNISIE	TUNISIE	2
oct-13	Orthopedics	USA	USA	2
déc-13	Orthopedics	FRANCE		3
janv-14	Electronic parts	FRANCE	35	1
mars-14	Orthopedics	SINGAPORE	SING	3.5
avr-14	Cardiac surgery	FRANCE	76	2
mai-14	Orthopedics	DK	DK	2
mai-14	telemedecine	FRANCE	75	1.5
juin-14	Vascular surgery	FRANCE	59	1
juin-14	Orthopedics	FRANCE	69	2
juil-14	Digestive surgery	FRANCE	59	1
oct-14	Orthopedics	USA	USA	2
déc-14	Orthopedics	FRANCE	59	2
déc-14	general equipment	FRANCE	14	2
déc-14	Orthopedics	TUNISIE	TUNISIE	2
janv-15	Electronic parts	FRANCE	35	1
janv-15	Orthopedics	USA	USA	2
févr-15	IVD MD	FRANCE	91	3
mars-15	Orthopedics	SINGAPORE	SING	3.5
avr-15	Cardiac surgery	FRANCE	76	2
mai-15	general equipment	Belgique	Belgique	2
mai-15	Cardiac surgery	SUISSE	SUISSE	2
juin-15	Orthopedics	DK	DK	2
déc-15	general equipment	FRANCE	14	2
janv-16	Electronic parts	FRANCE	35	1
févr-16	IVD MD	FRANCE	91	3
févr-16	radiology	FRANCE	67	2
mars-16	Electronic parts	SINGAPORE	SING	3.5
mars-16	Electronic parts	Malaysia	MAL	1
mai-16	Orthopedics	DK	DK	2
juin-16	Cardiac surgery	FRANCE	76	2
juin-16	Vascular surgery	FRANCE	59	1
juin-16	Orthopedics	FRANCE	69	2
nov-16	ophtalmic surgery	FRANCE	67	1
sept-17	Digestive surgery	FRANCE	69	3

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janv-17	Electronic parts	FRANCE	35	1
mars-17	DMDIV	FRANCE	91	3
mars-17	sterilisation	FRANCE	89	1
avr-17	Orthopedics	DK	DK	2
mai-17	Digestive surgery	Allemagne	ALL	2
sept-17	Orthopedics	FRANCE	63	1
nov-17	Vascular surgery	FRANCE	59	1
déc-17	Medical equipements	FRANCE	56	1
févr-18	radiology	FRANCE	67	2
mars-18	DMDIV	FRANCE	91	4.5
avr-18	Cardiac surgery	FRANCE	76	4
mai-18	Audioprothesis	FRANCE	17	1
mai-18	Orthopedics	DK	DK	2.5
sept-18	Orthopedics	FRANCE	94	2.5
oct-18	Cardiac surgery	FRANCE	76	1
déc-18	Medical equipements	FRANCE	56	1
Avr-19	Cardiac surgery	FRANCE	76	4
Mai-19	Orthopedics	DK	DK	2

❒ CONSULTING SERVICES

YEAR	Description of services
2018	○ Support to analyze and evaluate the impact of new MDR – Class III medical device ○ Support to analyze and evaluate the impact of new MDR - Class IIa medical device ○ Support to analyze and evaluate the impact of new MDR - Class I medical device
2017	○ Support to maintain the certification ISO 13485 / General equipment ○ Support to analyze and evaluate the impact of new version 2016 of the ISO 13485 – electronic parts supplier
2016	○ Support to implement UDI regulation / FDA – Electronic medical device Class II ○ Evaluation of the new EU regulation for medical device and quality system application ○ Evaluation of new ISO 13485 : 2016 and determination of an associated action plan ○ Support for the registration of a new product following CE mark procedure – dental instrument – Class I
2015	○ Support to improve the risk management process (ISO 14971 standard) - Abdominal wall reinforcement prosthesis – class IIb ○ Support to update technical file for CE Mark – Class IIb – Solution for ocular lenses ○ Support for the registration of a new product following CE mark procedure – dental instrument – Class I ○ Feasibility Study for determining the clinical and biocompatibility strategy – combined medical devices Class IIb ○ Feasibility study for determining the regulatory strategy to put on the market a new product to measure the intracranial pressure – Class III
2014	○ Support for preparation of risk management file according to ISO 14971 standard for the registration of medical devices (ocular implants) in Australia. ○ Support for preparation of ANVISA inspection – Class III active medical device ○ Support for registration medical devices in Mexico – Class II medical device ○ Support for updating technical documentation for CE Mark – Abdominal wall reinforcement prosthesis ○ Support for registration medical devices in Japan – Class II active medical device ○ Support for CE registration and reimbursement – Class I devices for treatment of bedsores. ○ Support for registration medical devices in Canada – Class II medical device

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	○ Support for ISO 13485 Certification – Class II robotic equipment ○ Support for ISO 13485 Certification and CE Mark – Class III biological implants
2013	○ Support for preparation of ISO 13485 certification – Robotic solution for the manipulation and organization of catheters or supple instrument – **France** ○ Support for writing technical documentation for CE MARK – software medical device - **France** – France ○ Support for preparation of ISO 13485 certification – Biological prostheses – **France** ○ Support for updating technical documentation for CE Mark – Abdominal wall reinforcement prosthesis – **France**
2012	○ Support for Medical device registration in Japan – Orthopedic devices - **France** ○ Support for writing technical documentation for CE MARK – Orthodontic devices – **France**
2011	○ Support for FDA Inspection – Packaging of medical devices - **France** ○ Support for writing technical documentation for CE MARK – Ophthalmology - **France** ○ Support for writing technical documentation for CE MARK – Spine - **France** ○ Support for writing 510[k] file and associated documentation – Spine – **France**
2010	○ Support for preparation to ISO 13485 certification – Subcontractor for spinal implants manufacturing - **France** ○ Protocol of validation – Packaging process for sterile spinal implants – **France** ○ Risk management process related to the implementation of an activity of packaging in a controlled area – Subcontractor for implants treatment - **France** ○ Support for analysis and treatment of materiovigilance events / exchange with competent authorities –Implantable medical devices - **France**

❒ TRAINING

ADEQUAT EXPERTISE is registered as a training organism (in France) : Number of activity declaration 54 17 01405 17 (under Poitou-Charentes administration representative).

YEAR	Trainings
2019	New MDR: understanding the new requirements
2018	ISO 13485: 2016 – New requirements to implement and to audit
2018	New MDR: understanding the new requirements
2017	To conduct quality audits for internal and external program
2017	ISO 13485: 2016 – New requirements to implement and to audit
2017	21CFR Part 820 requirements
2016	To conduct quality audits for internal and external program
2016	ISO 13485: 2016 – New requirements to implement and to audit
2015	How to implement a risk Management process according to NF EN ISO 14971 v 2013
2015	Understanding the medical device regulation context: ISO 13485 – European directive – 21CFR PART 820
2014	To conduct quality audits for internal and external program
2014	How to implement a risk Management process according to NF EN ISO 14971 v 2013
2014	Industrial process: implementation of a strategy of validation IQ – OQ - PQ
2013	To conduct quality audits for internal and external program
2012	To conduct quality audits for manufacturing processes and subcontractors
2012	To conduct quality audits for internal and external program
2011	Quality Management: Comparison of requirements between the main applicable standards (US, Canadian and European standards)
2010	To conduct quality audits for internal and external program
2010	ISO 13485: 2016 – New requirements to implement and to audit
2010	How to implement a risk Management process according to NF EN ISO 14971 v 2013