



Integra MicroFrance
Le Pavillon
03160 St Aubin Le Monial

WHO ARE WE ?



Integra is active in more than 50 countries

Founded in 1989, Integra is one of the international leaders on the medical devices market. Headquartered in Plainsboro (United States of America / New Jersey), Integra is listed on the NASDAQ Stock Market (IART) and achieved a 928.3M\$ turnover in 2014. Integra now operates in more than 100 countries with its distribution network and has a taskforce of 3500 people all over the world.

Integra develops, manufactures and distributes implants, instruments and medical devices for neurosurgery, spine surgery, extremity reconstruction, reconstructive plastic surgery and general surgery.

Integra is dedicated to limiting uncertainty for surgeons, so that they can concentrate on providing the best patient care.

Integra MicroFrance

Integra MicroFrance designs, manufactures, controls, distributes and repairs active or non-active surgical instruments, including electrosurgical instruments, dedicated to general surgery or specialized surgeries such as Ear-Nose-Throat surgery, plastic surgery, laparoscopic surgery.

Integra MicroFrance has a taskforce of more than 100 personnes in its manufacturing facility in Saint-Aubin le Monial (03160), in the middle of France. MicroFrance devices are distributed in 35 countries.

History :

- 1970 Creation of the company Ets BOUTMY – MICROFRANCE at Bourbon l'Archambault (03160)
- 1992 Setting up of MICROFRANCE in a new building at Saint-Aubin-Le-Monial (03160)
- 1999 / 2000 Acquisition of MICROFRANCE by groupe XOMED Group / XOMED group is acquired by MEDTRONIC Group
- 2014 Acquisition of MICROFRANCE by Integra LifeSciences
- 2017 Inauguration of a 1000 square meters new building dedicated to machining

Our products :

<p>ENT (Ear-Nose-Throat) Instruments: Laryngoscopes / Forceps / Microsurgery, etc.</p>	
<p>Laparoscopic Instruments : Electrosurgical forceps / Trocars, etc.</p>	
<p>Instruments for plastic surgery and general surgery : Osteotomes / Mallets / Dissection forceps / Scissors, etc.</p>	

OUR QUALITY POLICY



Quality Policy

The companies of Integra LifeSciences stand for integrity – of our people, our products and our partners.

- We are committed to providing life saving products that are safe and effective.
- We are committed to continuously improve the effectiveness of our Quality Management System, our products and our services.
- We are committed to meeting the regulatory requirements and to satisfying the needs of our customers and partners.
- We strive to deliver high quality products and services to achieve total customer satisfaction.

The products manufactured by the companies of Integra LifeSciences provide state of the art medical technology that improves the quality of life for the patients we serve.

A handwritten signature in black ink, appearing to read "Peter J. Arduini".

Peter J. Arduini
President and Chief Executive Officer

OUR ENVIRONMENTAL POLICY



E-MAQ-03d (EN)

**Security and Environmental Policy
Integra MicroFrance**

Create, develop, produce and deliver the most suitable products to our customers, notably in term of environmental requirements.

Make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals while privileging a sustainable development.

Recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company's success.

Satisfy all requirements and regulations concerning the environment and safety, as well as the other applicable requirements.

Take all necessary actions to sustain and continually improve the effectiveness and adaptability of the quality, security and environmental management systems.

Initiate a process for protecting the environment, including a better use of natural resources, a better prevention of pollution and globally a sustainable improvement of our impact on the environment.

September 20th, 2017

Director of Operations
Pierre DE TAILLANDIER

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OUR QUALITY & ENVIRONMENTAL COMMITMENTS

Our main certifications & applicable regulatory requirements

Quality

- **ISO 13485 Certification** - Medical Devices– Quality management systems -- Requirements for regulatory purposes
- **French & European regulatory requirement EC Certificate / Approval of full Quality Assurance System ANNEX II** excluding section 4 Directive 93/42/EEC concerning medical devices; French Code of public health
- **American regulatory requirements (FDA)** - Quality System Regulations (QSR) – 21 CFR Part 820
- **Canadian regulatory requirements** - Canadian Medical Device Regulation (CMDR)
- **Other regulatory requirements** depending on the final geographical destination for our products

Environment

- **ISO 14001 Certification** –Environmental – Requirements with guidance for use
- **European & French regulatory requirements (French Code of Environment)**, including regulation on « Installations Classées pour la Protection de l'Environnement (ICPE)»

Our quality approach with our suppliers:

- **Selection & follow-up according to the type & criticality of the products / services provided including :**
 - ✓ Self assessment concerning quality, environment & processes/technologies
 - ✓ Agreements : quality agreement, framework agreement, distribution agreement, non disclosure agreement
 - ✓ Audits at regular intervals
- **Establishment of purchasing specifications:** Instructions / Drawings / Specifications / Design brief etc.
- **Documentary requirements for purchase** order according to the type of product / service provided: Delivery note / Certificate of Conformity / Raw material Certificate, etc.
- **Performance monitoring** on the quality performance based on quantities delivered and/or the delivery performance
- **Incoming inspection** adapted to the performance of the supplier and/or the criticality of the product in order to determine the conformance of the products supplied with the purchasing specifications.
- **Development of partnerships** with our more competitive suppliers.

Our environmental approach with our suppliers :

- **Favor local suppliers/subcontractors** in order to minimize the environmental impact of raw materials of our products.
- **Purchase steel of European origin**
- **Purchase eco-friendly & sustainable supplies** (Ecolabel /FSC / PEFC, etc.).

- **Encourage an environmental approach among our suppliers** with the promotion of ISO 14001 certification and / or the establishment of measures aiming to reduce the impact of the company and its activities on the environment.
- **Identify ways to reduce/find alternatives to the packaging of purchased products**, i.e. packaging reuse, packaging recycling.

CONTACTS

Purchasing

Raw materials / Machined components / Service deliveries / Utilities

Nathalie FRIAUD
+(33) (0)4 70 67 98 03
nathalie.friaud@integralife.com

Instruments

Maeva DORIATH
maeva.doriath@integralife.com
+(33) (0)4 70 67 37 64

Quality

Thérèse SUN KRYS
+(33) (0)4 70 67 37 58
therese.sunkrys@integralife.com

Environment

Nathalie DATIN
+(33) (0)4 70 67 37 68
nathalie.datin@integralife.com