



Annual  
Report  
**2019**

# Annual Report 2019





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Front cover photo:

**Chison Liu,**  
*Process Development Engineer II*  
He is based in Bedford, MA USA.



## President's Letter

Dear All,

It has been a great honor to serve Werfen as its President in 2019. I would like to thank the Board of Directors, my brothers and all of you for your trust and support during the past 12 months. It has been a truly rewarding year for me.

2019 was another successful year for Werfen; one in which we focused heavily on continuous improvement, for the Company as well as our customers.

We concentrated on R&D, an area that was close to my father's heart and an important part of our mission at Werfen. We increased our R&D investment to ensure that we continue to offer the most advanced instruments, reagents and services to our healthcare partners.

We also completed our second biennial, global, employee engagement survey, *Werfen Voices*. It asks our greatest asset, our people, where we are succeeding as a company, and where they believe opportunities exist to further improve—ensuring we all have a hand in shaping our future. I am pleased to report that our survey response rate was 93%—very similar to 2017. The figure surpasses the average response rates of other companies our size.

One key area highlighted in both *Werfen Voices* surveys, was the need for enhanced communication. I am pleased to say that we have made significant strides in this regard. Last year we implemented several key communication initiatives, including regular President's letters and CEO Talks videos. They allowed us to communicate our new Mission, Vision and Strategic Objectives, and were very well received. I also want to highlight our Intranet, *WeNet*. This platform has been integral in bringing us all closer through storytelling and sharing. It has also provided a way for everyone to access relevant information quickly and easily.

Our future success, in terms of performance and results, goes hand-in-hand with our continued commitment to our Values. Guiding us for more than five decades, these Values shape who we are and how we work together. They are what differentiate us from other companies. We all share the responsibility of keeping our Values alive.

Great companies like Werfen succeed because of *Great People*. Daily, I am inspired by our employees around the world. They are united as never before to help in the fight against COVID-19. It is thanks to their tenacity that Werfen can ensure that our product lines and plants are at the ready supporting healthcare professionals as they manage patients' care.

I close this message with sincere gratitude to all our employees and thank them for their continuous efforts and ongoing commitment to Werfen. We have enjoyed another year of strong results, exciting new projects and successes, all of which are made possible by their dedication to delivering the best-in-class products and services to our healthcare partners.

Sincerely,



**Marc Rubiralta**  
President

## CEO Message

Dear All,

I am very pleased to report that 2019 was another strong year for Werfen. We brought new products to market, advanced our R&D pipeline and delivered solid financial results. Our core business, *in vitro* diagnostics (IVD), grew 6.5%, driven mainly by Hemostasis, Acute Care Diagnostics and Autoimmunity.

As it has for more than five decades, our focus continues to be the support of our customers and their patients around the world.

In 2019, sales, in constant currency terms, totaled €1,472 million, an increase of 6.1% versus 2018. We take great pride in our financial performance because we know what is behind the numbers: clinical laboratories around the world using Werfen systems and reagents to test more than 1.6 million patient samples a day.

The well-being of patients is what moves us to bring new products to market each year, improving care and overall efficiencies in the healthcare industry. It is what drives our activities from the point of product development to market launch and beyond. For that reason, we are committed to investing in R&D. In 2019, we increased spending in this area by 11%.

We are living in a moment in time when the work we do is at its most critical. COVID-19 is testing our passion and determination to advance medical science. I want to personally thank each-and-every-one of our employees worldwide for their tireless efforts. It is thanks to the support they provide to healthcare professionals treating patients that Werfen is making a difference.

As we seek to advance our mission to improve laboratory medicine worldwide, we rely on a highly engaged workforce globally and its passion and commitment for providing the outstanding level of professionalism which characterizes us. The results of our 2019 employee engagement survey, *Werfen Voices*, confirms this.

Giving back to society is also integral to how we do business. In 2020, we will announce our first, global Corporate Social Responsibility (CSR) program. In cooperation with an internationally recognized non-governmental organization, in need of healthcare and educational support, our global CSR program will build a sense of community, collaboration and solidarity across Werfen. Without replacing local initiatives it will reinforce our One Werfen, One CSR program.

I want to thank all of Werfen's employees for their commitment. No matter where in the world they are located, or what role they play; their contributions have had a tremendous and positive impact on our results. Our people will always be the key to Werfen's success and continued ability to deliver the value our customers expect from us.

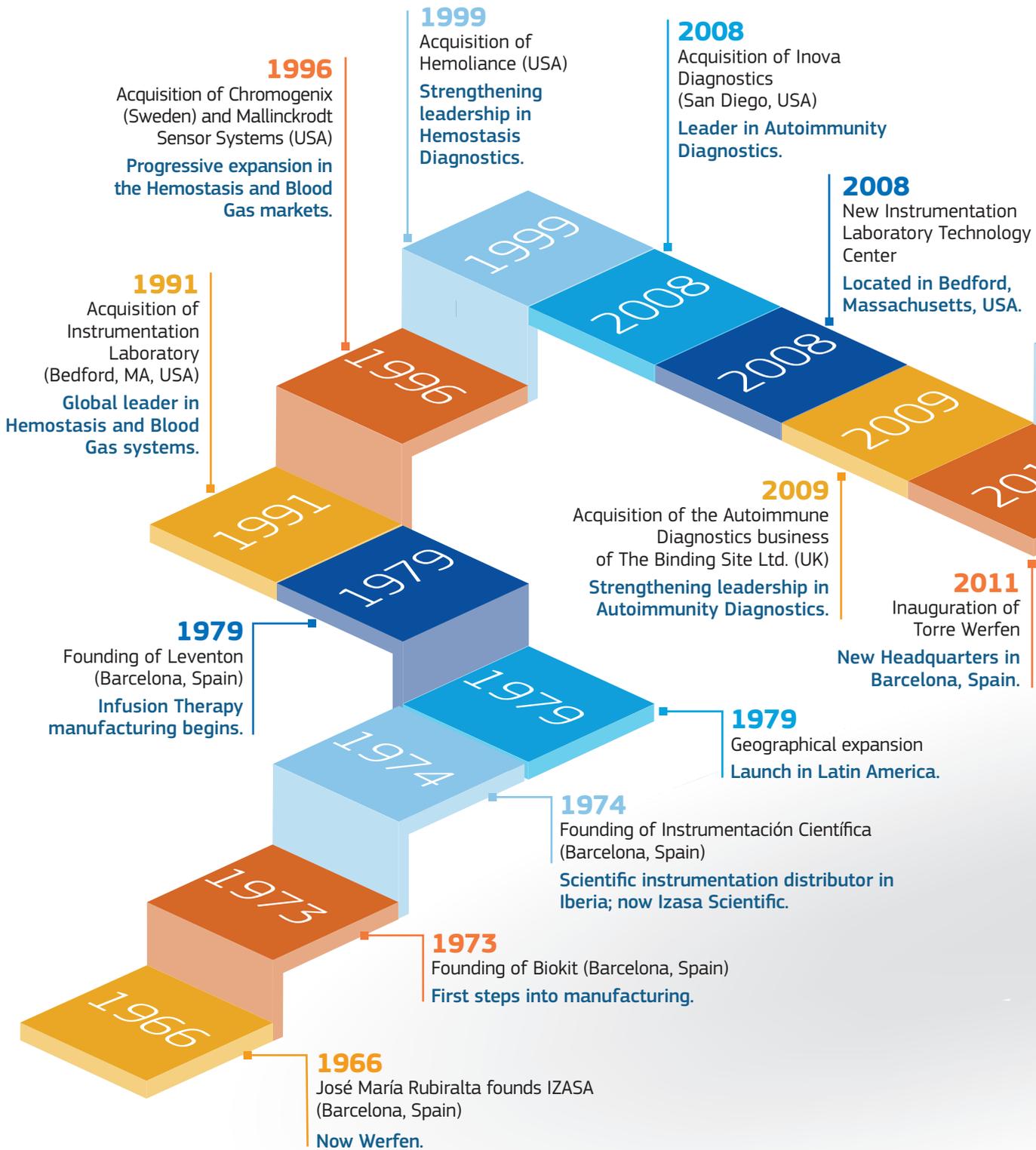
Sincerely,



**Carlos Pascual**  
CEO



## Our History



20  
20

**2012**

The Next Generation

Jordi Rubiralta  
appointed  
President.

**2019**

Handover of presidency  
Marc Rubiralta appointed  
Werfen President

**2017**

New Biokit Technology Center  
Located near Barcelona, Spain.

**2017**

Acquisition of Accriva Diagnostics (USA)  
Global leader in Whole Blood Hemostasis  
testing at the point-of-care.

**2016**

New Logistics  
Center for Iberia  
Located in Tarancón,  
Cuenca, Spain.

**2016**

Acquisition of TEM® (Germany)  
Expertise in viscoelastic technology and Patient  
Blood Management at the point-of-care.



## Our Ethos



### Mission

Our Mission is to improve the quality of laboratory medicine worldwide.



### Vision

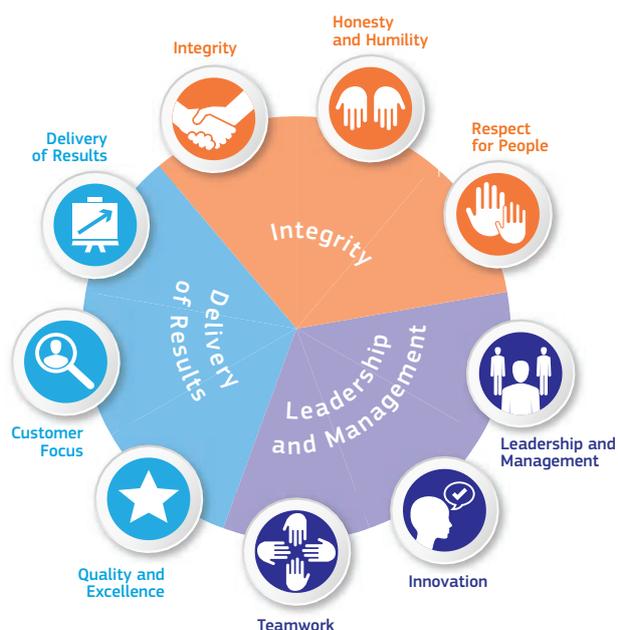
Our Vision is to be the first choice of the most advanced laboratory and point-of-care customers worldwide; delivering best-in-class *in vitro* diagnostic solutions for specialized disciplines—through innovation, quality and engagement of the best talent—to enable better patient care and improve healthcare efficiency.



## Our Values

In September 2018, *Werfen Values* were officially launched worldwide. We proudly celebrated these Values during Value Day with posters, flyers and roll-ups. They showcased the corporate morals which define our business.

These Values, which have been guiding us for over 50 years, are the essence of our business that shape who we are, how we work together, and define the behaviors that drive our success.



### Integrity

We strive to demonstrate open, honest and ethical behavior in all dealings with our customers, clients, employees, suppliers, partners, general public and government bodies.

### Respect for People

We recognize that people are the most important part of our business. We value the contribution, thoughts, ideas, differences and diversity others bring, and show the utmost respect for everyone we interact with.

### Honesty & Humility

We endeavor to be open, honest and reliable and listen to others as we communicate, building trustworthy relationships inside and outside the organization. We aspire to be humble about how we approach our work and our achievements.

### Leadership & Management

We seek to inspire and motivate our employees in their work, aligning their objectives and goals with the Vision and Strategy of Werfen, through frequent formal and informal communication.

### Teamwork

We understand our unique contribution to the business and we work together to achieve common goals, helping and supporting others along the way and striving for high performance in everything we do.

### Innovation

We encourage our employees to execute better or different ways of doing things that derive greater value for our customers and stakeholders, as well as to make processes and systems more efficient and effective.

### Delivery of Results

We all take responsibility for the delivery of results and achievement of success at an individual and team level. In knowing what is expected of us, we strive for top performance in everything we do.

### Quality & Excellence

All our business practices, processes and systems are designed to achieve quality results that exceed the expectations of all our stakeholders. We work to the highest standards in everything we do and hold others accountable for ensuring these same levels of excellence.

### Customer Focus

We involve our customers through the full product development lifecycle to ensure we deliver true value through our portfolio of solutions; we provide the support they need through constant communication; and we do all of this because behind every blood sample there is a human being.

## Our Structure

Werfen is a global leader in *in vitro* diagnostics (IVD) with a long-term commitment to providing innovative solutions for hospitals and commercial laboratories for the improvement of patient care.

Werfen is a growing, privately held corporation founded in 1966, in Barcelona, Spain.

## The Team

### Worldwide Employees

	2019	2018
Employees	<b>5,254</b>	5,072

### Activity

	2019	2018
Sales & Administration	<b>53%</b>	53%
R&D	<b>11%</b>	11%
Operations	<b>36%</b>	36%

### Geographical

	2019	2018
Europe	<b>44%</b>	44%
North America	<b>40%</b>	42%
Rest of the World	<b>16%</b>	14%



# Business

## Corporate



Headquarters in Barcelona (Spain)

## IVD



A Werfen Company

Main Office, R&D and Manufacturing Facilities in Bedford, Massachusetts (USA)  
 R&D and Manufacturing Facilities: Orangeburg, New York (USA); San Diego, California (USA); Munich (Germany)  
 Manufacturing Facilities: Ascoli (Italy)

- Hemostasis
- Acute Care Diagnostics
- Clinical Chemistry



A Werfen Company

Main Office, R&D and Manufacturing Facilities in San Diego, California (USA)

- Autoimmunity



A Werfen Company

Main Office, R&D and Manufacturing Facilities in Barcelona (Spain)

- OEM
- Infectious Disease Serology



Diagnostic Solutions for Life

- Clinical Software
- Affiliates

## Medical Devices



A Werfen Company

- Infusion Therapy



A Werfen Company



A Werfen Company



A Werfen Company



A Werfen Company

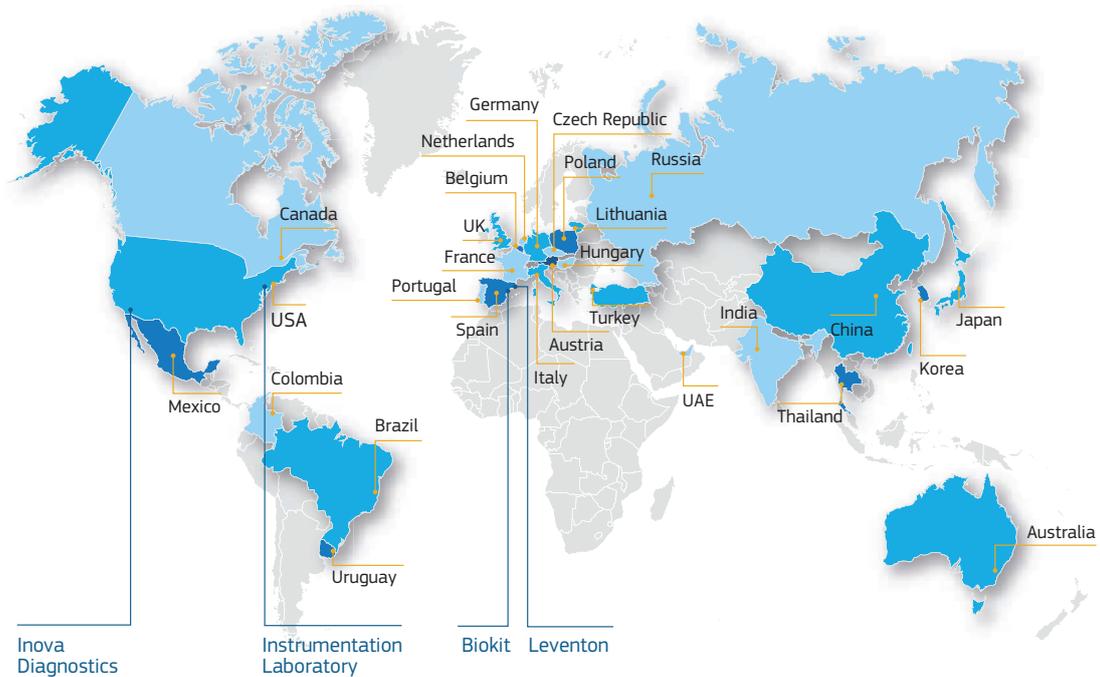


A Werfen Company

- Medical Devices & Scientific Instrumentation Distribution

# Locations

Werfen has a direct presence in around 30 countries, and in more than 100 territories via distributors.



## Corporate Social Responsibility

### Changing Lives

#### Spanish employees support UN initiative

To kick-off the holiday season, a time for giving back and being thankful, colleagues in Spain donated their time in support of the United Nations #Companies4SGDs campaign. More than 150 companies around the world support this global initiative, which seeks to eradicate poverty, protect the planet and assure prosperity for all by 2030.

Over 95 employees participated in activities ranging from: cooking for the handicapped; coaching women who are preparing to return to workforce; spending time with the elderly; working with the homeless; and gathering trash off of local beaches. The unique experiences brought our people together as a team, introduced colleagues from different departments to one another and strengthened our commitment as corporate citizens.



#### Can Montcau breakfast market raises funds to cure rare diseases

In December, Biokit and Clinical Software employees organized a breakfast market at their offices which are located just outside of Barcelona.

The group raised funds from the sale of the home-made baked goods like cakes, pizzas, muffins, sandwiches and omelets. The money was donated to a local television station which sponsors research projects dedicated to finding cures for rare diseases.

#### The Ronald McDonald House (USA)

Every day The Ronald McDonald House Charities (RMHC) provides lodging, meals, a family care center, education, and a home-away-from-home for families with children being treated for serious, often life-threatening conditions at local hospitals.



The generosity of volunteers and donors make it all possible. In return, guest families are asked to make a donation for each night's stay to help continue operations for future guest families. When one of its own – Catherine and Aaron Llanes were in need of RMHC's services – colleagues from Inova Diagnostics Quality Assurance and Regulatory Affairs (QA&RA) rose to the occasion.

The team of volunteers assembled 96 Welcome Bags for families like the Llanes' so that they would feel at home during their stay at RMHC. The reusable cloth bags contained toiletries including toothbrushes, toothpaste, lip balm, lotion, tissue packs, hair combs as well as puzzles, activity books, card games, and a stuffed toy to help pass the time.



Biokit and Clinical Software matched the donation euro-for-euro.



## In 2020, we will announce our first, global Corporate Social Responsibility (CSR) program.

Our new global CSR program will be an exciting addition to, and in no way replaces -- the numerous local philanthropic endeavors our companies and affiliates have supported for many years. It will offer all employees the opportunity to come together in support of a single, enterprise-wide program, as requested in our 2019 employee engagement survey, *Werfen Voices*.

**In cooperation with an internationally recognized non-governmental organization (NGO) in need of healthcare and educational support, our global CSR program will build a sense of community, collaboration and solidarity across Werfen. It will reinforce One Werfen, One CSR program.**



## Working with us



An Interview with Lucía del Moral Haworth,  
VP of Corporate Human Resources  
and Communication

**The Corporate Human Resources (CHR) department contributes to our Company's overall success and to that of its employees, through leadership and excellence in Human Resources management.**

**The following is an interview with the VP of Corporate Human Resources and Communication Lucia del Moral Haworth, who reflects on her six years at Werfen, and discusses where the Company is today, and will be in the future.**

**You have been at Werfen for six years. How would you describe them?**

They have been very exciting and fast paced. The Corporate Human Resources and Communication function had not existed before. During my first year I spent a great deal of time travelling around the world getting to know the business, the different companies and affiliates and, more importantly, the people. During that year we created an initial five year plan to build the foundation of the Human Resources Corporate function through different processes such as Performance Management, Talent Management, our employee engagement survey (*Werfen Voices*), *Werfen Values*, etc., ensuring they became embedded across the organization with the support of our people managers. We also launched quite a few Corporate Communication initiatives including new and visually attractive websites. We introduced our intranet, *WeNet*, along with additional communication channels and tools that enable employees to be aligned with the strategy and direction of the Company as well as general news of interest.

We are now tackling the next level of projects which are related to Managerial Effectiveness and an Employee Value Proposition that will continue to grow and develop our people. We are also thrilled to be launching our first global Corporate Social Responsibility program which I am sure will generate a great deal of interest worldwide.

**In what ways is the Culture, set by founder José María Rubiralta, alive and present?**

This is a great question. Our culture is driven by the late José María Rubiralta. This is his legacy and our heritage. The founder's passion was always about improving patient health. He was a

visionary who started with very little but had an instinct for the market and a strong commitment to long-term investment. He possessed the spirit of imagination, the highest levels of energy and a 'go-for-it' attitude. His leadership was characterized by his tenacity, patience, ambition, hard work, humility and long-term vision. I am proud to say, this is who we are today.

Werfen is a multinational company and as such, strongly oriented towards the delivery of results. We are fast-paced and highly customer-focused. These drivers blend very nicely with our culture: supportive, nurturing, open and friendly.

I would describe our employees as smart. They have great academic backgrounds, are hardworking, humble and excellent leaders and team players. They also bring a great blend of strategic and tactical skills with them. People are willing to roll up their sleeves, dive in and fix an issue. These are the employees who understand the culture here and are successful.

**Attracting top talent is a priority. How does Werfen identify and attract talent?**

Our preference is to develop and promote internally rather than recruit externally. It is the way to acknowledge and recognize our employees for their excellent performance and commitment to the Company. However, given Werfen's growth (organically and through M&A) we need to attract talent in several different ways.

For specific positions we may reach out to executive search companies. We also leverage social media such as LinkedIn, internal referral programs, universities and business schools, and our career page on our Web.

**What is the next HR challenge?**

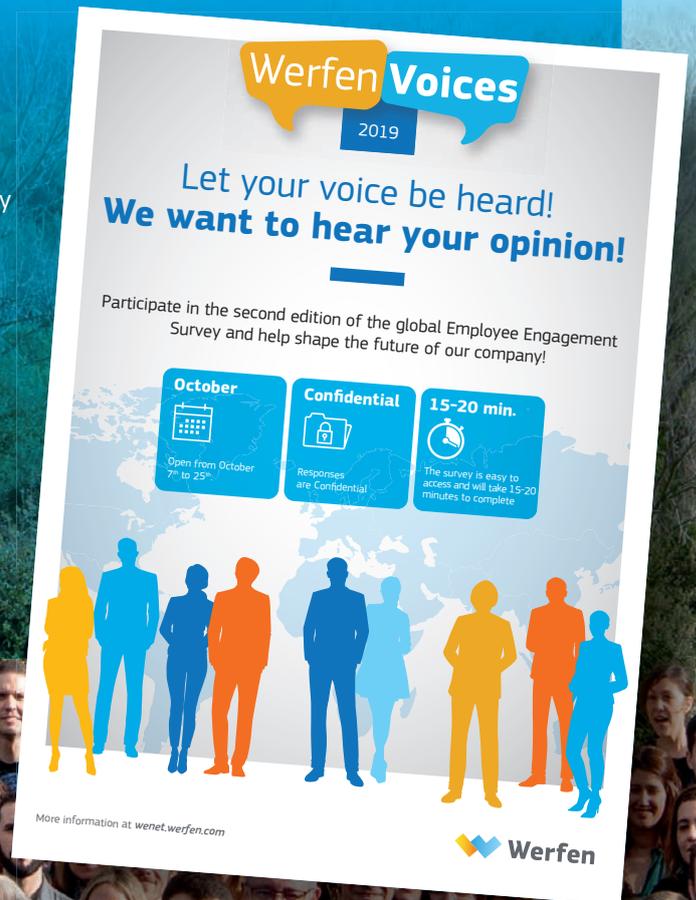
There are many exciting challenges ahead of us at Werfen. To highlight one, it would be raising the bar in managerial effectiveness. We depend so much on our people managers: they recruit, onboard, develop and manage our talented employees. If they understand the Company's overarching strategy, they will explain it to their direct reports. If they understand change, they will share the why, the what and the how with their people. Our employees work hard and deserve the best manager, one who provides them with a positive experience from the first moment they come on board.

## Why work with us

### Werfen Voices

The first employee engagement survey, *Werfen Voices*, was launched in 2017, as part of Werfen's continued commitment to being an excellent place to work. This survey asks employees, our greatest asset, to share their thoughts and insights and to provide feedback on what they believe is working effectively at the Company and where they see opportunities for improvement, or change.

In 2019, we conducted the second *Werfen Voices* survey, which allowed us to measure the effectiveness of the actions implemented from our first *Werfen Voices* Survey and understand where we can continue to make improvements.



The poster features the Werfen logo at the top, followed by 'Werfen Voices 2019'. The main headline reads 'Let your voice be heard! We want to hear your opinion!'. Below this, it says 'Participate in the second edition of the global Employee Engagement Survey and help shape the future of our company!'. Three key points are highlighted in blue boxes: 'October' (Open from October 7<sup>th</sup> to 25<sup>th</sup>), 'Confidential' (Responses are Confidential), and '15-20 min.' (The survey is easy to access and will take 15-20 minutes to complete). At the bottom, there are silhouettes of diverse people and the Werfen logo with the text 'More information at [wenet.werfen.com](http://wenet.werfen.com)'.



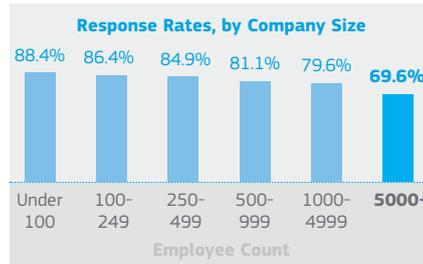
1



## Response Rate

# 93%

**of employees participated in the survey.** This is a tremendous achievement given that 2019 was the second time the survey was administered, and we had 800 additional employees join the Company as a result of our latest acquisitions.



According to Quantum

The figure is significant because it **surpasses the response rates of other companies** our size; the benchmark is 70%.

2



## Objectives & Strategy

# 75.5%

of employees responded favorably to the statement: **The Objectives & Strategy of Werfen are clear.**

The response rate is significant because it indicates that Werfen's Objectives, Mission & Vision and Strategy are being socialized effectively, and more importantly **employees feel connected to them.**

3



## Extraordinary Progress

was made in all aspects of **Communication**, which was **up 13.54% over 2017.**

Werfen remains committed to communicating with its employees in a clear, complete and concise manner which reflects our Values and policies;

4



# 81%

**of our employees said they feel engaged**, meaning they have a willingness, and the ability to contribute to Werfen's success as well as its Mission, Vision and Values.



5



Statements such as **"I understand how my job helps my organization achieve success"**, **"I am proud to work here"**, **"I am treated with dignity and respect"** received the **highest favorability ratings.**

## José María Rubiralta Award



### What is the José María Rubiralta Award?

The José María Rubiralta Award, named in honor of our founder, recognizes significant initiatives and extraordinary achievements of employees. It is presented annually to an individual or team.



**The José María Rubiralta Award was presented to the entire Australian team and General Manager Sally Hickman.**



**The team of Werfen in Australia**

Since the formation of our affiliate in Australia in 2012, the team has achieved exceptional results, year-after-year. In 2019, they secured one of the largest contracts in our corporate history—the Hemostatis business at New South Wales (NSW) Health Pathology with 72 ACL Top® Family 50 Series systems.

This huge success resulted from extraordinary teamwork and collaboration across the Company. Above all, it was a stellar display of seamless cooperation among the Australian Team.



**Marc Rubiralta, Sally Hickman and Carlos Pascual**

"It is an honor to receive the José María Rubiralta Award on behalf of the Australian team and myself. To be recognized in this way for our success brings an incredible sense of pride to each team member. We are a young company, having started operations here in 2012, and our year-on-year achievements reflect the passion and determination we all have for what we, as a company, are able to deliver to healthcare in Australia. I am proud to lead this team as we firmly establish ourselves as a leader in all our business."

**Sally Hickman**

## Our Governance

Werfen operates under the supervision of the following decision-making bodies:



Germán  
Castejón

Luis  
Cantarell

Carlos  
Pascual

Marc  
Rubiralta

### Board of Directors

The primary decision-making body, responsible for the administration and representation of Werfen.

#### **Marc Rubiralta, President**

Bachelor of Business Administration; MBA  
11 years at Werfen:

- 2 years in Finance, in Iberia;
- 3 years as Finance Director in China;
- 5 years as President of the Medical Devices division
- President of Werfen since January 2019

#### **Jordi Rubiralta, Director**

Bachelor of Economics, MBA  
15 years at Werfen (2003-2018)

- 8 years in several management positions in IVD and Medical Devices, Finance, and leading the European team
- 7 years as President

#### **José Luis Rubiralta, Director**

Bachelor of Economics, MBA  
9 years at Werfen (2006-2015)

- 4 years in Critical Care Marketing
- 2 years in Financial Control
- 3 years managing Internal Audit and Group Compliance

#### **Xavier Rubiralta, Director**

Bachelor and Master of Biotechnology; MBA  
8 years at Werfen (2009 - 2017)

- 4 years in R&D at Biokit
- 4 years in Corporate Marketing at Instrumentation Laboratory in the United States

#### **Carlos Pascual, CEO**

Bachelor of Law; MBA  
32 years at Werfen

- 4 years as Director of Operations at Clinical Lab
- 5 years Director of Finance and 10 years as Senior Vice President at Instrumentation Laboratory in Italy
- 6 years Senior Vice President at Instrumentation Laboratory Worldwide except North America and General Manager IVD Iberia
- 7 years as CEO at Werfen

#### **José Luis Guerrero, CFO**

Bachelor of Business Administration; MBA  
18 years at Werfen

- 15 years as Financial VP of IVD business in the US
- 3 years as CFO, Werfen

#### **Germán Castejón, Independent Director**

Bachelor of Business Administration, MBA

- 21 years in banking sector
- Expert in the field of Finance and Family Business

#### **Luis Cantarell, Independent Director**

Bachelor of Economics

- 25 years at Nestlé and member of the Board of Directors
- Expert in Health and Nutrition

#### **Miquel Roca, Non-Director Secretary Director**

- Corporate Lawyer
- Expert in the field of Law and Family Business



José Luis Guerrero

José Luis Rubiralta

Xavier Rubiralta

Jordi Rubiralta

Miquel Roca

### Executive Committee

The Executive Committee has the full executive powers of the Werfen Board of Directors, which have been expressly and permanently delegated to it in full, excepting only those powers that cannot be delegated in accordance with applicable laws or bylaws.

- **Marc Rubiralta, *Chairman***
- **Carlos Pascual, *Member***
- **José Luis Guerrero, *Member***

### Audit and Control Committee

This committee reports directly to the Werfen Board of Directors to monitor and report on activities related to Compliance and the Werfen Code of Ethics, internal and external audit, and risk management.

- **José Luis Rubiralta, *Chairman***
- **Jordi Rubiralta, *Member***
- **Xavier Rubiralta, *Member***
- **Miquel Roca, *Member***
- **Germán Castejón, *Member***

### Appointments and Remuneration Committee

This Committee is responsible for informing and assisting the Board of Directors on issues related to its composition, remuneration and fulfillment, succession plans and remuneration of first executives and other issues related to remuneration policies and talent management, as requested by the Board of Directors.

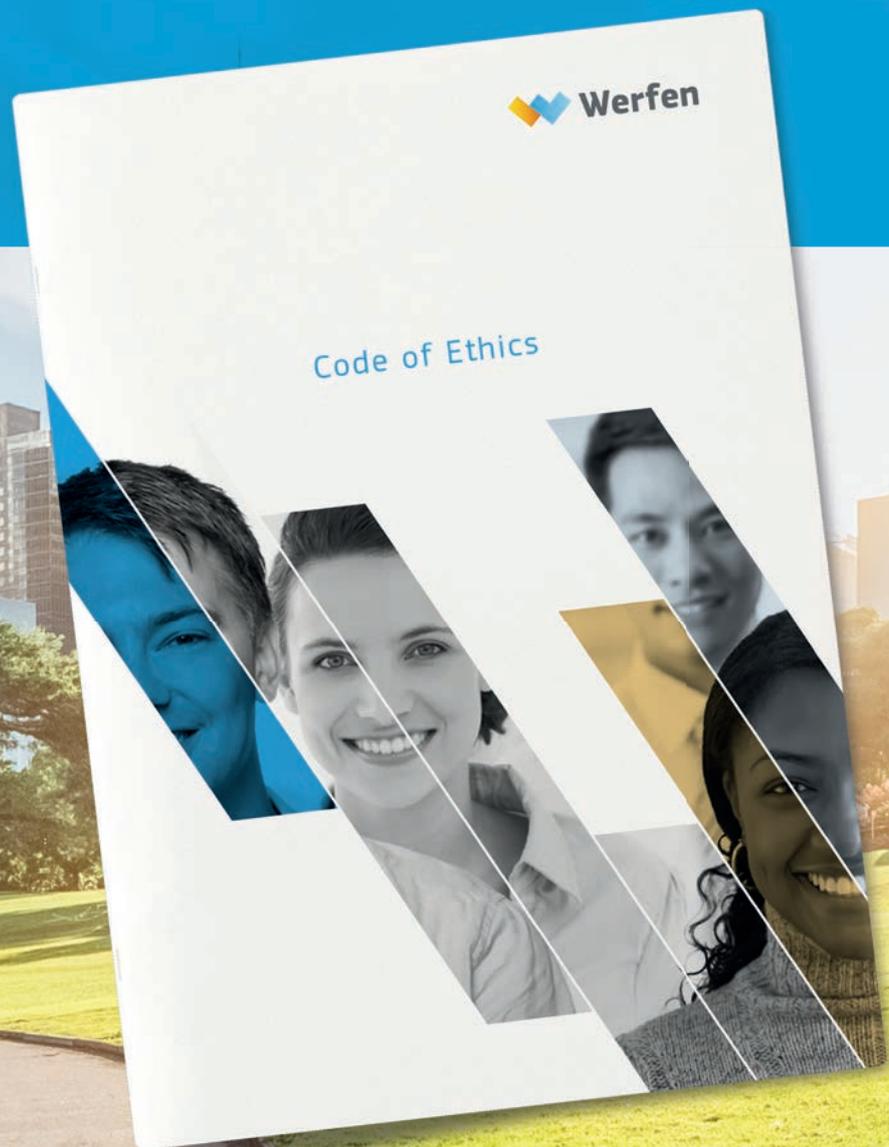
- **Marc Rubiralta, *Chairman***
- **Jordi Rubiralta, *Member***
- **Xavier Rubiralta, *Member***
- **Carlos Pascual, *Member***
- **Miquel Roca, *Member***

## Our Governance

### Compliance Department

This department is responsible for preparing, monitoring, and managing all topics related to compliance and the Werfen Code of Ethics, including adhering to existing internal and external rules and regulations.

Compliance Officer Albert Garicano and our local compliance officers are committed to ensuring that our Company's Code of Conduct is consistently complied with worldwide.





## A look back on 2019 with Albert Garicano

“Werfen’s mission is to improve the quality of laboratory medicine worldwide. To realize this mission, we need to earn and maintain the trust of all our stakeholders: healthcare partners, customers, employees and the society we serve.”

Our Code of Ethics clearly expresses practical guidance and references regarding how to comply with laws, regulations and our policies. It also reaffirms the values guiding our actions, enabling us to make the right choices in every situation.

In 2019, we launched a new compliance training program that will strengthen our governance. This program, together with the Code of Ethics, the Compliance Manual, the Ethical Channel, the Audit Program and the Compliance Body constitute the Werfen Compliance Program, which is designed to safeguard our Company's reputation.

**Albert Garicano**  
Compliance Officer



## IVD

*In vitro* diagnostic (IVD) testing is performed outside of the body, using blood, bodily fluid or tissue samples. IVD is invaluable to medical professionals worldwide, allowing rapid diagnosis and monitoring of conditions, with minimal discomfort or risk to the patient. IVD testing yields significant benefit, as well as cost-efficiency, impacting approximately 70% of all medical decisions, but accounting for just 2% of the global healthcare spend.

Werfen is a world leader in IVD and our systems, reagents and data management solutions. Healthcare providers around the world depend on our products in hospitals, commercial laboratories and in acute care settings -- emergency departments, intensive care units, operating rooms, cardiac catheterization laboratories and interventional neuroradiology suites — testing over 1.6 million patient samples each day.

## Our products support management of patients with COVID-19

In December 2019, the World Health Organization was alerted to an unusual pneumonia. The new virus, COVID-19, quickly evolved from a "public health emergency of international concern" to a global pandemic.

The COVID-19 pandemic has had a profound and devastating impact on people and healthcare all around the world. Many of Werfen's key products play an essential role in the management of patients suffering from this deadly virus.

- **Blood Gas:** GEM® Premier™ blood gas systems play a crucial role in the management of hospitalized patients with COVID-19. In the words of Instrumentation Laboratory's Medical Director: *"Arterial blood gas analysis is critical in evaluating and monitoring respiratory function in patients with pneumonia, acute respiratory failure, and acute respiratory distress syndrome. Patients with COVID-19 can suffer from these disorders and require routine blood gas testing as part of their care, especially if they require mechanical ventilation. With the global pandemic of COVID-19, GEM Premier Blood Gas analyzers and cartridges are essential to help avoid devastating consequences."*
- **Hemostasis:** Guidance for the evaluation and risk-stratification of patients with COVID-19 includes several of our HemosIL® assay products: D-dimer, Prothrombin Time (PT), and Fibrinogen Degradation Products (FDP).

- **Whole Blood Hemostasis:** The most seriously ill patients with COVID-19 may receive extracorporeal life support (ECLS), Monitoring Hemostasis at the point of care with the Hemochron Signature Elite analyzer is essential to assuring proper heparin anticoagulation and the prevention of potentially life-threatening complications.
- **Patient Blood Management:** As a result of the COVID-19 pandemic, there has been a significant decrease in blood donation. Blood shortages can have devastating consequences for the most seriously ill patients. Hospitals have reacted to the shortage by emphasizing blood conservation. Our ROTEM® systems play an integral role in accomplishing this objective.

Werfen would like to acknowledge the hard work of all our employees worldwide for their tireless efforts to provide our customers with essential products and support during this global pandemic. Their passion and dedication for patient care is demonstrated each-and-every day. Their work has made, and continues to make, a true difference and contribution to the care that patients with COVID-19 so desperately need.

**We are proud of them, our Company and our products. Thank you.**

## Autoimmunity: A patient's story

**Inova Diagnostics is a leader in Autoimmunity, with a specific focus in Antiphospholipid Syndrome (APS), an autoimmune disease which causes a coagulation disorder, resulting in thrombosis and pregnancy loss.**



Jeanine Cervantes

**We are delighted to share Jeanine Cervantes' story of her patient journey, which eventually led to her receiving an APS diagnosis, and finally being able to manage the disease.**

My APS journey began in 2010 with headaches, dizziness and balance problems. After several months, I went to see an internist, and then a neurologist, who suspected Multiple Sclerosis (MS). A series of brain MRIs were negative for MS. After a repeat brain MRI in 2011, I was diagnosed with a particular type of migraine that starts in the brainstem, or lower part of the brain.

I then found myself in the cardiologist's office, after having a malignant hypertensive crisis, which caused me to lose my vision in one eye. When the dizziness worsened, I returned to the neurologist, who ordered another brain MRI. The test revealed that my symptoms and changes seen on the MRI could indicate MS; so, spinal tap was ordered, which came back negative.

I decided to seek a second opinion. After reviewing my medical records, the second neurologist, a specialist in MS, was 100% certain that I did not have MS. I was elated!

My blood pressure eventually normalized, but I began to notice new symptoms. The most disturbing were the memory lapses. I decided to see an internist familiar with autoimmune disease. She ordered a comprehensive rheumatologic panel, and a consultation with a different neurologist. After reviewing my medical records and history, the rheumatologist immediately ordered an APS panel; **I later learned that Werfen's Autoimmunity business line develops tests to detect antibodies towards aCL, B2GP1, PS/PT and B2GP1 Domain 1.**

It was determined that all my symptoms were related to one problem – APS. Three major organ systems were affected; my brain, heart and lungs. In total, I had seen four neurologists, two internists, a cardiologist, a hematologist, a rheumatologist and an immune specialist. The good news: I finally had a diagnosis and I am on my way to successful disease management.

**"I am proud of the work that we are doing to advance science and aid in diagnosing diseases like APS with potentially life threatening complications like thrombosis."**



Michelle Terrell, MT (ASCP)  
Product Manager Reagents

## Hemostasis and Acute Care Diagnostics



**Ramon Benet**

CEO Instrumentation Laboratory

**Every day, more and more customers around the world choose our Hemostasis and Acute Care Diagnostics products and services, resulting in excellent revenue growth for these business lines.** This is the best evidence of the value our customers place in the quality of the products we develop, manufacture, distribute and support. Our products are second to none, and our people are second to none.

Contributing significantly to our Acute Care Diagnostics success in 2019, was the growth of our ROTEM<sup>®</sup>, Hemochron<sup>™</sup>, VerifyNow<sup>™</sup>, and Avoximeter<sup>™</sup> product lines, developed and manufactured at our newest IL Technology Centers in Munich, Germany and San Diego, California. This growth demonstrates the value these products bring to our customers and their strategic fit within our offering. Additionally, our flagship blood gas system, the GEM<sup>®</sup> Premier<sup>™</sup> 5000, continued its global rise, driving the best year ever for manufacturing and worldwide placements of GEM Premier systems.

In Hemostasis, the ACL TOP® Family 50 Series Hemostasis Testing System also continued its global market share growth, solidifying its number one position worldwide. And, we placed an unprecedented number of HemoCell™ Specialized Lab Automation workcells, significantly enhancing lab efficiency around the world.

Several new IL products were introduced in 2019. In Acute Care Diagnostics, the GEM Premier ChemSTAT™ system, designed for rapid basic metabolic panel (BMP) testing was released to select hospitals in the UK. This system provides results in just 70 seconds to help diagnose and manage many acute conditions, such as kidney failure and septic shock.

In Hemostasis, we released the HemosIL® AcuStar ADAMTS13 Activity assay, which aids in the diagnosis of Thrombotic Thrombocytopenic Purpura, a rare, but life-threatening, disease. This test can reduce the time to diagnosis from days to just 30 minutes, allowing informed and immediate treatment. These are both excellent examples of the impact our products have on patient care and the fulfillment of our mission to improve the quality of laboratory medicine worldwide.

In 2020, we look forward to completing key regulatory submissions and product releases across our product portfolios. And very importantly, we will remain focused on our customers and patients—they are at the center of what we do, and they fuel our passion for innovation. We understand and appreciate the trust and confidence customers place in us, and the critical importance of our testing solutions, for the very best patient care.

## Acute Care Diagnostics

Acute Care refers to the specialized management of life-threatening conditions requiring rapid, comprehensive patient care and frequent



monitoring, in intensive care units, emergency rooms, operating rooms, catheterization laboratories, and other clinical settings.

Through Instrumentation Laboratory, Werfen offers a synergistic testing portfolio of diagnostic solutions for the management of patients in Acute Care settings. When care cannot wait, our integrative Blood Gas, Whole Blood Hemostasis and Patient Blood Management cartridge-based systems, with quality management and connectivity solutions, deliver fast, actionable results—simply and easily—for enhanced patient outcomes and efficiency.

## Hemostasis

Hemostasis is the human body's natural physiological response to halt and prevent bleeding/hemorrhage; it is the balance of the interaction between blood coagulation proteins, platelets and the vessel walls, which maintains blood flow. Disorders or disturbances of these factors can cause bleeding or thrombosis, which can be associated with serious medical issues.



Through Instrumentation Laboratory, Werfen offers the most advanced automation and standardization of pre-analytical, analytical and post-analytical

Hemostasis testing processes, which enables healthcare professionals to make critical and often life-saving decisions for their patients.

## Autoimmunity



**Roger Ingles**  
CEO Inova Diagnostics

**2019 was a remarkable year for the Autoimmunity business line, in terms of performance.** Sales numbers continued to grow solidly, and every member of the business line did a great job reaching their goals.

Many factors contributed to the business line's good performance in 2019. Key among them – and stated objectives for the year – were increased sales in all geographies; the control of expenses; and continuous improvements in manufacturing and inventory management.

All these factors, together with the launch of new products, solidified Autoimmunity as an important pillar of Werfen's success.

As the business line grows, processes will evolve, and work will become more specialized to provide the excellent products and service that customers demand. In 2019, to support this growth and to enhance the customer experience, Autoimmunity created separate Technical Support and Complaint Handling teams. It also consolidated management of North America Technical Support and Field

applications. In addition, all commercial operations at the global business unit and Sales and Support in North America were integrated to allow for greater coordination, efficiency and innovation. With the integration of Business Development into R&D Autoimmunity will be able to continue exploring new business and product opportunities.

As always, the most important element of everything the business line does is its people. Autoimmunity has an extremely talented team; one committed to quality, continuous improvement and a culture of collaboration and support. 41 new employees were hired in 2019 and more than 50 employees progressed into new positions which offered them the opportunity to continue their professional growth and development.



## Autoimmunity

Autoimmunity refers to problems with the immune system, specifically when antibodies and immune cells target and attack the body's own healthy tissues by mistake. Any disease that results from such an immune response is labeled an autoimmune disease (e.g., celiac disease, lupus, rheumatoid arthritis). Autoimmune diseases can destroy body tissue, cause abnormal growth of an organ, or alter organ function. Autoimmune diseases affect approximately 8% of the population, 78% of whom are women, and are one of the top 10 leading causes of death in women under 65 years of age.

Through Inova Diagnostics, Werfen is a world leader in developing new systems and biomarkers which help laboratories improve the way patients with autoimmune diseases are diagnosed, followed-up and treated.



## Original Equipment Manufacturer



**Jose Luis Zarroca**  
CEO Biokit

**In 2019, Werfen's OEM business line grew with the signing of two supply agreements in two strategic markets, China and Japan.**

In the field of customized assays, the business line introduced 15 OEM assays for a strategic partner and reached an agreement to develop and manufacture nine new assays for one of the top-ranking IVD companies.

The business line's aim is to deliver the significant growth projected in the coming years: in 2019, it moved forward with a new organizational structure in its Research & Development, Sales & Marketing and Quality Assurance & Regulatory Affairs departments, building strong foundations for Biokit as a Center of Excellence in the field of immunoassays.

## Original Equipment Manufacturer (OEM)

Through Biokit, Werfen offers OEM solutions consisting of proprietary products and custom development and manufacturing services. Biokit is consistently rated a top-quality supplier, and as such, has strong partnerships with more than 80 long-term customers in the IVD industry that source immunoassays and biomaterials from us—in fact, six of the top 10 IVD manufacturers are our clients.

### 2019 Highlights

#### Customized Assays

- Commercial launch of six OEM Clinical Chemistry assays and nine OEM CLIA assays for a new platform of one of the top six IVD manufacturers;
- Agreement with one of the top five IVD players for the development and manufacturing of nine new assays;
- Design approval for the first FDA PMA assay;
- Agreement with an OEM partner to develop the next generation of two existing assays.

#### Biomaterials

- Biokit and Inova Diagnostics joined forces to form the Inova R-Unit. The new unit, which operates from Biokit's facilities in Spain, is the research arm of Inova Diagnostics biotechnology R&D group;
- Supply agreement with two top companies in strategic markets (China and Japan).

## Infectious Disease Serology

Our experience in a variety of IVD technologies allows us to offer a wide range of high-quality immuno assays, from our company Biokit, that help clinical laboratories and blood banks improve quality of care and facilitate disease diagnosis for infectious diseases and rheuma markers.



## IVD

### Clinical Software

We are committed to developing and supporting safe, efficient, and innovative clinical applications and laboratory instrumentation systems. **Our solutions enhance patient care and facilitate the management of information in hospitals and laboratories around the world.**

#### 2019 Highlights:

In today's world, cybersecurity and privacy are essential, particularly in healthcare, where it is key to keeping patients and providers safe. For that reason, in 2019, Clinical Software worked hand-in-hand with all three business lines (Hemostasis, Acute Care Diagnostics and Automimmunity) to develop secure products, and analyze and mitigate vulnerabilities within our product portfolios to protect our customers and patients.

Information technologies applications are also an important component of Clinical Software, and an integral part of Werfen's portfolio. In 2019, we successfully organized our first Clinical IT Support event. More than 30 IT support engineers attended the meeting, representing 17 affiliates. In addition to sharing experiences, success stories, and being trained on new corporate tools, the group harmonized deployment of our leading applications, including, among others:

- **HemoHub™**, a centralized management system for hemostasis testing;
- **GEMweb® Plus 500** which simplifies and centralizes point-of-care testing operations;
- **QUANTA Link®**, a data management system which provides immediate control of all autoimmune sample processing.

### Clinical Chemistry

We develop and support safe, efficient, and innovative clinical applications and laboratory instrumentation systems for clinical chemistry and toxicology.



#### 2019 Highlights

- **The clinical utility of Glycated Albumin**, as a midterm glycemic control marker, was recognized for glycemic control in type 2 diabetes mellitus patients. Information about this milestone can be found on Lab Tests Online. This is an important milestone for the marketing of quantiLab® Glycated Albumin kit.
- **New iLab® Aries**, a state-of-the-art desktop analyser for routine chemistry laboratories, was successfully launched in EMEA, Southeast Asia and Mexico. It is the ideal solution for laboratories interested in measuring specialty assays, like Glycated Albumin, on a dedicated analyser.

### Other IVD Products

In addition to our proprietary portfolio of IVD products, some of our affiliates (mainly Spain, Portugal and Mexico) distribute analyzers, reagents, and controls from internationally recognized partners. We are proud of these long-standing partnerships which allow us to bring IVD products essential to Molecular Biology, Microbiology and Applied Science.

This segment of our business continues to grow thanks to the specialized technical and application expertise in our affiliates.

# Medical Devices

## Medical Devices & Scientific Instrumentation Distribution

We distribute both our own and third-party medical devices like disposables, orthopedic implants, devices for endovascular procedures and solutions for oncology treatment, as well as third-party scientific instrumentation.

Through Izasa Scientific we market scientific instrumentation throughout Spain and Portugal for use in multiple applications in the life science, research, environmental control, and pharmaceutical, chemical and agro-food industries.

### 2019 Highlights

- **Izasa Hospital** received awards from several of its partners including Abiomed, Lumenis, APT Medical and MiTech for its extraordinary financial performance;
- **Medicinália-Cormédica** consolidated its leadership as a distributor of medical devices, achieving another record in turnover;
- **Nicolai** signed a new distribution agreement with BCM for the distribution of its stents for gastrointestinal applications;
- **Comesa Hungary** and Zimmer-Biomet strengthened their partnership by expanding their collaboration agreement to include sports medicine products;
- At **Izasa Scientific**, purchase order values increased 33%, reflecting the trust of important customers, like Centro Nacional de Biotecnología, for complex projects such as the installation of Spain's first electron cryomicroscope.

## Infusion Therapy

We develop and support safe, efficient, and innovative clinical applications and laboratory instrumentation systems for clinical chemistry and toxicology.

Through Leventon, Werfen offers single-use, continuous infusion systems, gravity flow regulators used in hospitals and infusion pumps used mainly in the treatment of ambulatory patients to promote patient recovery and improve quality of life by increasing patient mobility.

### 2019 Highlights

- **Celebration of Leventon's 40th anniversary** (1979-2019);
- **Launch of the new Dosi-Fuser® App.** This free downloadable multi-media training tool provides instructions for the proper use of our patented single-use, continuous infusion pump.
- **First European Distributor meeting;**
- **Ground breaking of a new factory**, which will be completed in mid-2021;
- Implementation of **new technologies and manufacturing automation**, improving product quality.



## Werfen World

Autoimmunity



**Bryan Hoenig,**  
Vice President Commercial  
Operations, North America

**2019 was an exciting year for Autoimmunity Commercial Operations in North America.**

Growth outpaced the industry average and was driven primarily by placements of BIO-FLASH®, QUANTA-Lyser® 3000 and NOVA View® and their associated reagents. We continue to position Aptiva®, a multi-analyte platform with new biomarkers, which will help clinicians increase their diagnostic confidence and laboratory efficiency.

Hemostasis and  
Acute Care Diagnostics



**Brian Durkin,**  
Senior Vice President Commercial  
Operations, North America

**Hemostasis and Acute Care Diagnostics (ACDx) Commercial Operations in North America**

exceeded budget and **achieved record growth** thanks to best in market products, a highly trained commercial staff and ongoing process improvements. Hemostasis and ACDx grew 8% and 11%, respectively. Growth was supported by record GEM® Premier™ blood gas testing systems and reagent sales.



**Jaume Serra,**  
Vice President EMEAI and  
Latin America

In 2019, as they have for many years, these **two regions successfully met their budget goals** in terms of Operating Income for each of Werfen's three business lines. Overall growth was outstanding in each region with relevant growth coming from various EU countries. Contributing to this success were improvements made to commercial capabilities with an emphasis on Value & Strategic Selling as well as clinical and IT capabilities.



## 2019 Region Sales

The regions, which include dedicated country-specific teams, are organized into five regions - North America, China, Asia Pacific, EMEAI and Latin America.



**Gilles Castera,**  
Vice President China

To meet the demands of a dynamic marketplace and to anticipate new trends, **Werfen in China continued strengthening its go-to-market strategy in 2019.** As a result: HemoCell™ can be found in many of China's largest hospitals; GEM® Premier™ 5000 is poised for a successful launch in 2020; and BIO-FLASH® is quickly becoming a reference for antiphospholipid syndrome testing.



**Ted Maione,**  
Vice President Asia Pacific

### **Asia Pacific exceeded budget and grew sales by 9.3% in 2019.**

Operating Income was also up 12.1% year-over-year. In addition, the region expanded its employee-base by 8% with a focus on Acute Care Diagnostics (ACDx) and Autoimmunity. Many of the new hires have been directed toward ACDx organizations to optimize important synergies in this product line.

## Quality & Regulatory



"We strive to be synonymous with Quality. It is a key driver of our success."

**Marc Bellosta,**  
VP Corporate QA/RA

**We strive to meet the highest quality standards across all business lines and geographies to comply with the most stringent regulatory and compliance requirements worldwide.**



### Our Quality Policy

**Our Quality Policy, derived from our corporate values, is at the core of everything we do and consists of the following principles:**

- Marketing products of the highest quality, which employ the latest technology;
- Ensuring the needs of our customers are always met, and legal and regulatory requirements fulfilled;
- Staying at the forefront of advances in technology, allowing us to provide state-of-the-art solutions to our customers;
- Offering efficient and customized post-sales services, including ongoing user training, specialized technical services, and a helpline for inquiries and equipment repairs;
- Promoting a positive work environment;
- Encouraging the organization to live by these quality objectives;
- Improving the quality of life of patients through innovation.

## ISO Certificates

### ISO 9001 and 13485 Quality Systems

The ISO 9001 is the world's most widely used ISO certification and ISO 13485 is the most popular certification among medical devices companies. Both systems demonstrate that our product/service-related processes maintain the highest possible standard.

All our manufacturing facilities, logistics centers, distribution companies and corporate services are certified.

### ISO 27001 Data Safety Systems

The ISO 27001 external certification validates that Werfen safeguards the security of all its assets, including financial information, intellectual property, employee data, and information entrusted to the Company by third parties. This standard has been certified by our affiliate in the UK.

### MDSAP Certification

The Medical Device Single Audit Program (MDSAP) is a program that allows a single regulatory audit of a medical device manufacturer's quality management system, satisfying the requirements of multiple regulatory jurisdictions. Audits are conducted by auditing organizations authorized by the participating regulatory authorities to audit under MDSAP requirements.

A single audit, the MDSAP enables medical device manufacturers compliance with standards and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan, USA.

Our IVD manufacturing facilities in all five countries are MDSAP-certified for product marketing. The program's main mission is to "... jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

### International Registrations

Our products are registered with the competent authorities in many countries worldwide, for marketing in those countries. As such, the Company's manufacturing sites comply with country-specific regulations (e.g., FDA (USA), CE (Europe), ANVISA (Brazil), NMPA (China), MFDS (South Korea), PAL (Japan), TGA (Australia)).

### International Healthcare Manufacturers Organizations

Werfen is an active member of various international associations for Medical Device/IVD manufacturers (e.g., MedTech (Europe), Advamed (USA), FENIN (Spain)).

### ISO 14001 Environmental Systems

This certification acknowledges that the organization strives to manage its environmental responsibilities in a systematic manner and in compliance with international and local environmental regulations. Our manufacturing sites located in Bedford, Massachusetts (USA) and Orangeburg, New York (USA), and our logistics centers in Roncello, Lombardy (Italy), and Tarancón, Cuenca (Spain), are ISO 14000-certified.



# Financial Results

Sales in 2019 reached € 1,472 million, representing 6.1% growth over 2018 in constant currency terms.

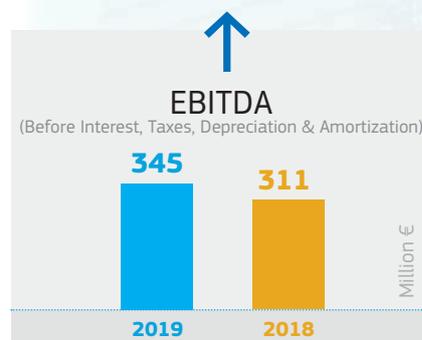
	2019	2018	Growth <sup>1</sup>
	M€	M€	%
IVD	<b>1,289</b>	1,183	6.5
Medical Devices	<b>183</b>	176	3.4
<b>Total</b>	<b>1,472</b>	<b>1,359</b>	<b>6.1</b>

<sup>1</sup> Constant Currency



	North America	Latin America	Western Europe	EEMEAI Eastern Europe, Middle East, Africa and India	Asia-Pacific
Growth	7.2%	4.8%	1.8%	6.7%	12.9%
Total Sales	27%	7%	40%	8%	18%





Financial Information before adoption of IFRS 16

# Annual Report 2019

Science, Passion and People defines us.