

# Annual Review 2021



**werfen**



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# President's letter

Dear All,

2021 was an eventful year, as we introduced a structural change and began operating as One Company. This new way of presenting ourselves to external stakeholders is a fundamental shift in our global positioning and in how we interact with one another across our organization. In addition, it will enhance and improve cross collaboration.

Last year was also the right time to carefully consider and define our Purpose, why we exist as a company. To that end, we launched a global project involving all our stakeholders. We began by surveying our Senior Leaders and Board of Directors to understand their views. We also considered the opinions of our customers, and, finally, our employees.

Shaped by all of us, our Purpose is rooted in our history and culture and is an integral part of our brand. It is what inspires and connects us and reinforces a sense of belonging and identity with Werfen.

Our Purpose Statement is: *We contribute to the advancement of patient care around the world through innovative specialized diagnostics.*

Equally – *Powering Patient Care* – our company tagline, links to our Purpose Statement and highlights that our products inform and drive the critical patient care decisions that clinicians must make.

Like our Values, our Purpose is at the heart of what we do. It is a tremendous responsibility that has been motivating us since my father founded the company more than 55 years ago.

It is the reason why we exist as a company.

Werfen's future also depends on our commitment to the sustainable social and economic growth of the countries where we operate. It is one of the many reasons why we became a signatory member of the UN Global Compact, the world's largest, voluntary corporate sustainability initiative. We support the UN Compact as an integral part of our values and our commitment to operating to the benefit of the world we all share.

If you are interested in this topic you can learn more in our 2021 Sustainability Report.

In closing, I want to recognize and thank every member of the Werfen team. All of them gave their time and energy to sustain us. The last two years were very complex. And it is humbling to know just how much our solutions have served society and the key role they played in supporting patient care. Despite it all, we came together as a team, and we were able to support our customers and their patients, without exception.

Thank you very much and I hope you enjoy our 2021 Annual Review.

Sincerely,



**Marc Rubiralta**  
President





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# CEO's message

## **2021 was a momentous year for Werfen. And I am pleased to tell you why.**

We began operating as One Company to reinforce our long-term strategy and growth.

Our commercial success continued its positive upward momentum last year, across all of our business lines and all of our geographies, posting double-digit growth in most of them.

We defined our Purpose, the reason why we exist. We achieved very good results in our global employee survey. We finalized our Strategic Plan which will guide us for the next three years.

Let me elaborate a little more on these last two points.

Regarding the global employee survey, the results showed that 88% of our employees are engaged with Werfen, which fills me with tremendous pride, and great optimism for our future.

Our new Strategic Plan is designed to allow us to retain our identity and leadership in our core businesses through significant investments in R&D, while exploring new markets, developing a digital strategy, attracting best talent, and accelerating growth. The strategic moves of this plan will also allow us to become a stronger organization, supported by our Culture, Values and People.

All these achievements combine to allow us to say that 2021 was a momentous year for Werfen.

We could not have accomplished it without the hard work, dedication, and passion of our people.

It is thanks to our people that we can look back on 2021 and feel very proud of our successes.

To learn more about Werfen, our successes in 2021 and our future plans, please read and enjoy our digital Annual Review.



**Carlos Pascual**  
CEO



# 01

## Purpose, Vision & Values

Our Purpose, Vision and Values combine to inform why we do what we do, where we are going and the spirit and behaviors that will take us there.





# Purpose statement

We contribute to the advancement of patient care around the world through innovative Specialized Diagnostics.



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## About our Purpose

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Patient care lies at the very heart of what we do.

Right now, throughout the world, hospitals and clinical laboratories are processing patient blood samples with our systems, reagents and data management solutions. And we know that behind each of these samples, there is a patient whose care may depend upon the quality of the test results.

Therefore, we strive to achieve the highest quality standards for all our products, the very best to ensure that our customers can rely on accurate and actionable information, for the very best patient care.



## Powering Patient Care

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Linked to our Purpose, Powering Patient Care, embodies the impact of our products, support and service, on patient care—informing and driving critical patient management decisions clinicians make every day.

**werfen**  
Powering Patient Care



# Our Vision

Our Vision is to be the first choice of the most advanced laboratory and point-of-care customers worldwide: delivering best-in-class 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

Our Values have been guiding us for 56 years and continue to do so. They 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.

# One Company

Our One Company approach represents a natural evolution for Werfen, strengthening our global leadership position in Specialized Diagnostics, and positively impacting our ability to drive innovation and support our customers.

Through one global identity, with the same vision and strategic objectives, our teams around the world can maximize collaboration to set new standards for products and services in Hemostasis, Acute Care Diagnostics, Autoimmunity, and Original Equipment Manufacturing (OEM).

# werfen







This is the  
Werfen brand

**The Werfen brand is much more than a logotype. It represents a new strategy, a new culture and a renewed way of facing the future.**

With its optimized brand architecture and renewed visual identity, Werfen aims to achieve a unified global presence that maximizes and strengthens brand equity across the entire portfolio.

# 02

## History of innovation

Thanks to our continuous investment in R&D and dedicated specialized teams, we have been at the forefront of decades of landmark discoveries, including the first direct-reading pH/blood gas analyzer and the invention of CO-oximetry, the first fully automated coagulation system, as well as more than 50 biomarkers in the autoimmunity market.





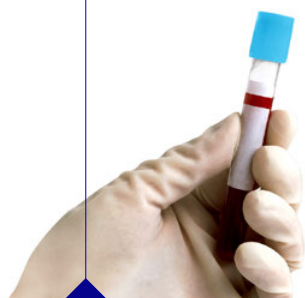


# History of innovation

**1959**

**IL 105**

First direct reading pH/ blood gas analyzer.



**1964**

**IL143**

First Flame Photometer Revolutionized chemistry electrolyte testing in the laboratory.

**1985**

**ACL 810 system**

First fully automated mid-sized Hemostasis analyzer.



1959

1963

1964

1967

1981

1985

2000

**1963**

**IL113**

First blood gas analyzer for routine clinical testing.



**1981**

**IL1303**

First blood gas analyzer with video-display and continuous calibration.



**1967**

**IL182**

Invention of CO-Oximetry.



**2000**

**GEM Pr 3000**

First stand gas testing with multi-u





## 2009 ACL AcuStar® System

First and only fully automated, high-sensitivity system with chemiluminescence for Hemostasis testing.

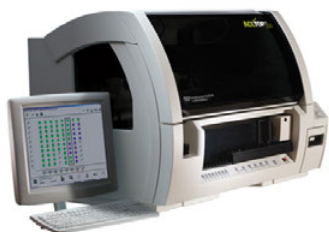


## 2020 Aptiva®

Aptiva is a fully automated multi-analyte system that represents the next generation of high throughput instruments for the clinical laboratory.

## 2004 ACL TOP Family Series

First fully automated and standardized system for Hemostasis testing.



## 2015 ACL TOP® Family 50 Series Systems

Next-generation ACL TOP Family with pre-analytical sample checks.



2004

2006

2009

2013

2015

2019

2020

Premier

Standardized blood  
platform  
use cartridge.



## 2006 GEM® Premier™ 4000

First blood gas analyzer with multi-use cartridge and integrated CO-Oximetry.

## 2013 BIO-FLASH® Rapid-Response Chemiluminescent Analyzer

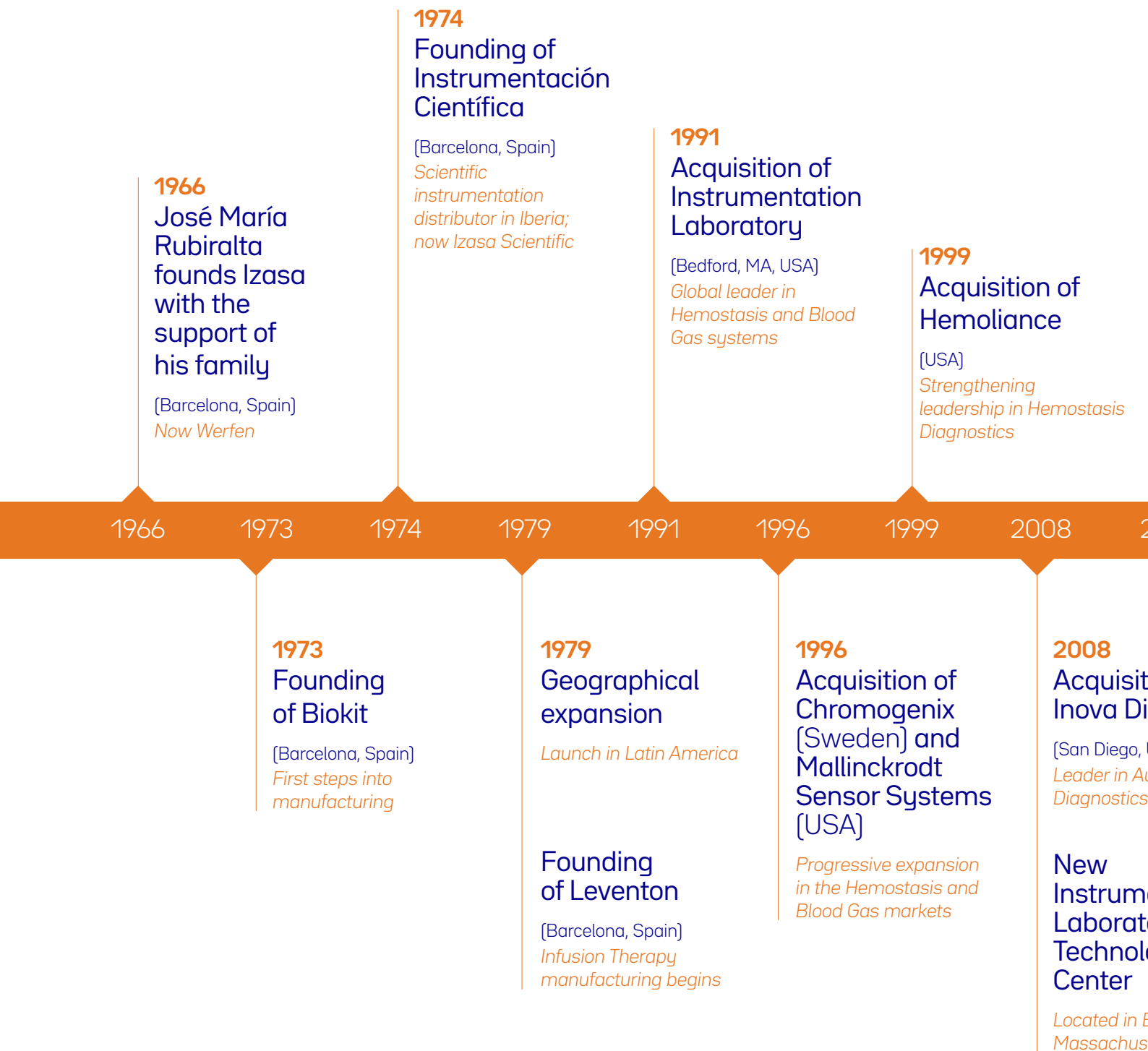
Full commercial launch of BIO-FLASH, for use by clinical reference and hospital laboratories. Tests previously requiring significant hands-on time automated on this intuitive and rapid system.



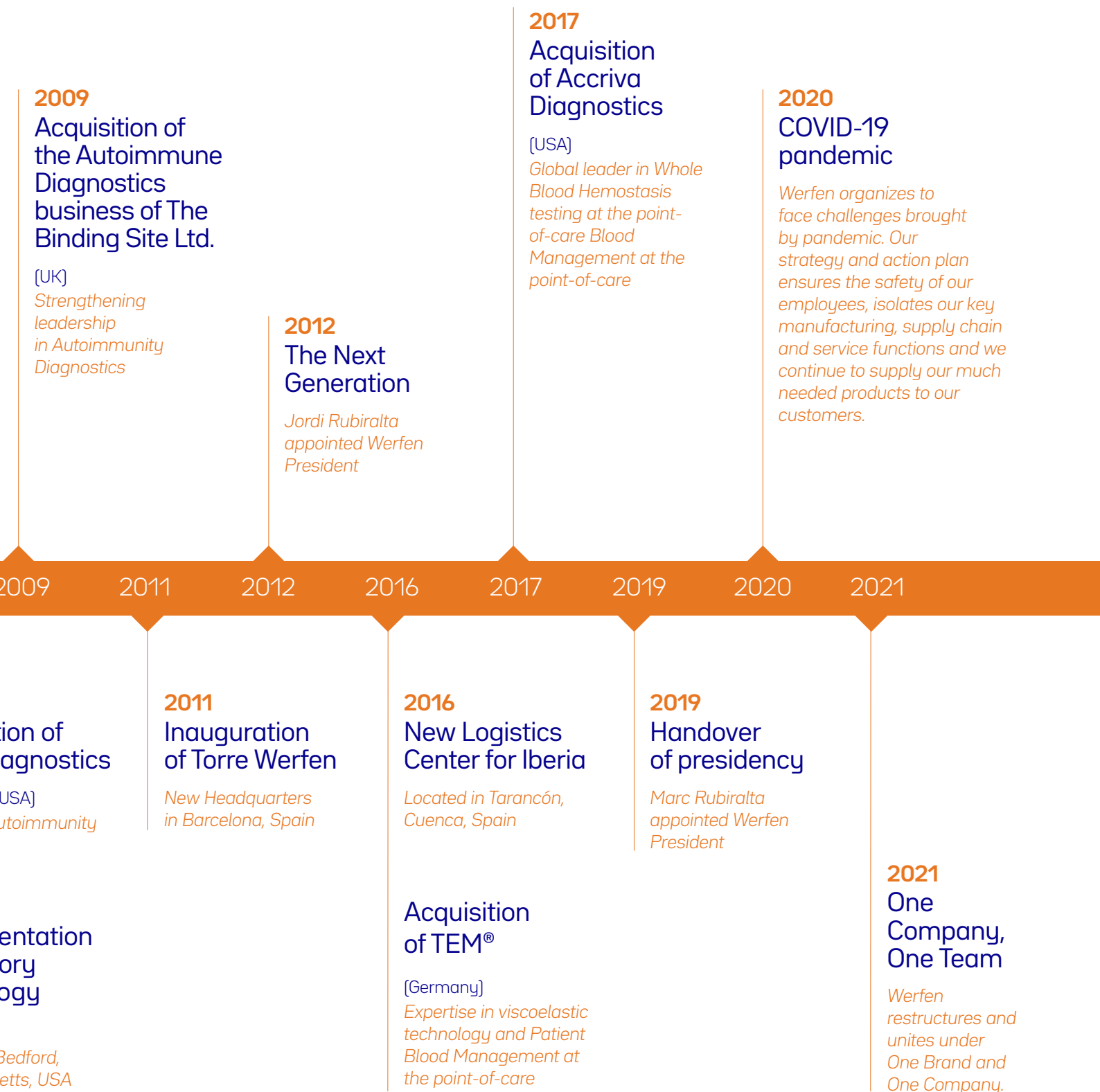
## 2019 GEM Premier ChemSTAT®

First multi-use cartridge analyzer with rapid, lab-quality BMP, including Crea, Hct, Lac, pH, and pCO<sub>2</sub>, in the ED.

# Werfen history







# 03

## People

Our talent is, without question, our most important asset. Our employees are the face of Werfen, and they represent our values in their day-to-day interactions with our stakeholders.



werfen





# Talent perspective



**Lucia del Moral Haworth**

VP Global Human Resources & Communications

Our people are the very definition of our culture and values: talented, intelligent, diligent and smart. At Werfen, every person counts and make a difference, and with us, commitment, passion, and great results are always recognized and rewarded.

Let me begin by saying how proud we are of our employees and their commitment to Werfen.

Our employees, very rightfully, have high expectations of us. They want the best leaders and managers; they want a purpose they can connect with and contribute to; they want growth and development opportunities; and they want the flexibility to balance their personal and professional priorities. And, they want a working environment which brings out the best in them, every day.

So we – the Senior Managers – have a huge responsibility to make all of this happen.

So, how do we support our people?

We have an integrated approach to Talent which starts with creating a positive experience for new hires from the moment they join us with carefully crafted onboarding, development strategies because we want them to succeed.

Knowing how important a manager and leader is for each of our employees, for the last few years, we have been very focused on increasing Managerial Effectiveness across the company with many different initiatives, some ongoing and others that we have in the pipeline.

Do you know what our employees truly appreciate about working with us? It comes again and again through all our surveys: our values, culture and especially, teamwork.

If I had to define our culture I would say that our employees are smart, hardworking, dedicated, no-nonsense, humble people. They are all experts in their fields while remaining extremely humble and open to listening and learning from others.

We are a medium-sized company. Our employees are visible and have an impact. Our employees can be whatever they want to be.

If you are interested in joining Werfen please go to our Careers Page at [werfen.com](https://www.werfen.com).

# Life at Werfen

Here's what our people say about what it's like to work with us, their expectations, hopes and plans for the future.



**Kieran Pickles**  
National Sales Manager, Australia

*"My growth at Werfen has been unbelievable, I've been allowed to join many major projects of the organization."*



**Lorena Hernández**  
Marketing Analyst, Mexico

*"I have received the support of my leaders and colleagues to create, to innovate, to make campaigns and content."*



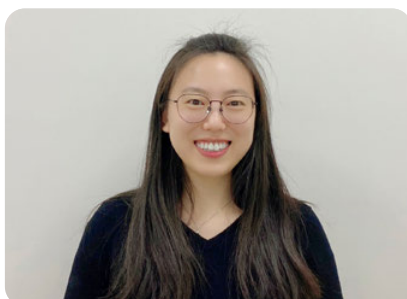
**Morgane Razafimahatrata**  
Product Manager IT Solutions, France

*"Werfen is continuously bringing innovation to the field of diagnostics."*



**Nancy Sheehy**  
National Director Corporate Accounts,  
North America Commercial Operations

*"Werfen is an amazing company, focused on innovation and transforming healthcare by improving patient care worldwide and creating healthier societies."*



**Vivi Pei**  
Account Manager, China

*"I think that Werfen offers its employees a platform filled with challenges and resources."*



**Zachary Hastings**  
Senior Programming Manager,  
North America

*"The collaboration across the entire organization sets us up to succeed."*

# Werfen Voices

In 2021 we conducted our third global, biannual employee engagement survey, *Werfen Voices*.

## Some key results from this survey

The survey gives our employees the chance to share feedback on what they believe is working effectively at the company and where they see opportunities for improvement or change. In common with the other surveys we conducted in 2017 and 2019, in 2021 we listened, we learned and we implemented actions based on employee feedback to make us an even better company to work for.

**86%**

Engagement

**86% of employees are engaged**

These are colleagues who have an average score in all their answers of over 4 [on a scale of 1 to 6].

**88%**

Participation

**The participation rate was an outstanding 88%**

The high rate means more representative and valuable data.

**70%**

Favorability

**The favorability percentage has increased noticeably**

This means 70% of all our collective responses were rated with a 5 "agree" or a 6 "strongly agree" [on a scale of 1 to 6]



# José María Rubiralta Award Special Edition 2020/21



The José María Rubiralta Award is our company's most prestigious honor. Presented annually, it is named after Werfen founder José María Rubiralta. It recognizes employees who excel at continuing his legacy of bold innovation and putting patient care at the core of everything we do.

Choosing a winner is difficult, but none so difficult as in 2020 and 2021. Nobody could have imagined the impact COVID-19 would have on the world, on all of us, or our customers. It is for these reasons we decided to acknowledge the outstanding contributions to our business with a very special edition of the award that combines the years 2020 and 2021.

The award was presented to 31 of our employees who represent all the functions and departments instrumental in delivering our products during the worst times of the pandemic.

These individuals have played, and continue to play, a key role in the end-to-end process of getting our products to our customers, beginning with Manufacturing, supported by our Medical Directors, continuing through Global Supply Chain, Sales Applications, Commercial Operations and Iberia.

Many congratulations to the individuals concerned and to the entire Werfen team for their resilience, resourcefulness and tireless dedication during an unprecedented period in our company's history.

Winning departments:

Manufacturing

Global Supply Chain

Commercial Operations

Sales Applications

Medical Directors

Spain & Portugal

# 04

## What we do

We are a worldwide leader in Specialized Diagnostics in the areas represented by our Business Lines: Hemostasis, Acute Care Diagnostics and Autoimmunity. Our Original Equipment Manufacturing (OEM) business line, is a leading researcher, developer and manufacturer of customized assays and biomaterials.





# Hemostasis

Empowering comprehensive hemostasis diagnostic management through advanced automation and standardization.



**Giovanni Russi**

COO, Hemostasis and Acute Care Diagnostics

Hemostasis Diagnostic Management is at the core of patient care. Our portfolio of analyzers, reagents and data management solutions is designed to help our customers with quality and standardization at every touchpoint. Our solutions in this area lead the industry, redefining the standard of care for bleeding and thrombotic disorders.

In 2021 our worldwide leadership position continued to grow, with solid shipments of ACL TOP® Family 50 Series, ACL AcuStar®, and ACL Elite® testing systems. Demand for HemosIL® D-Dimer assays remained high, and we saw growth across all HemosIL testing panels. Adoption of HemoHub™ Intelligent Data Manager, and our online educational platform, Werfen Academy, flourished.

In 2021, we also initiated the controlled commercial release of the ACL TOP 970 CL Hemostasis testing system, which uniquely combines world-leading Hemostasis technology with the unmatched analytical performance of chemiluminescence for on-demand availability of hemostasis test panels. We also initiated the commercialization in North America of the HemosIL Liquid Anti-Xa test kit to measure the direct oral anticoagulant, apixaban—marking the first FDA-authorized apixaban assay.

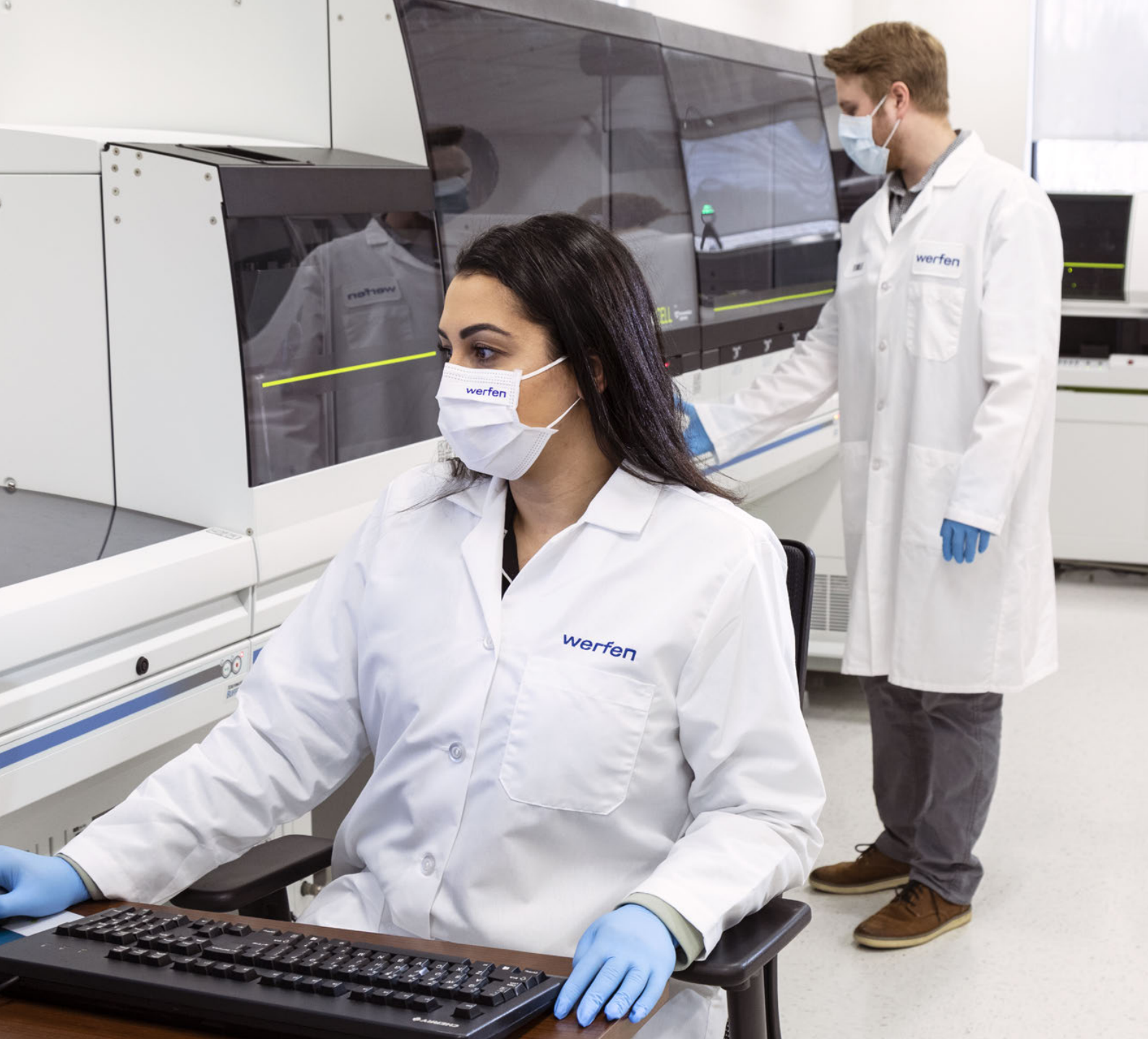
## Innovation



### ACL TOP® Family 50 series

A breakthrough in Hemostasis testing, ACL TOP Family 50 Series systems offer the most advanced automation and quality management, for routine to specialty assays. Designed for mid- to high-volume clinical laboratories, including those with Lab Automation tracks, all models are standardized for superior performance across the entire testing process. Automated pre-analytical sample-integrity checks, advanced quality and accreditation support and enhanced system security assure quality results and lab efficiency.

**Extending standardization beyond the analytical phase.**



Comprehensive line of *in vitro* diagnostic systems, including analyzers, automation, reagents, service, and digital solutions, to diagnose and guide treatment of thrombotic and bleeding disorders, designed to improve the quality of patient care, healthcare efficiency, and assure regulatory compliance in the clinical laboratory.



# Acute Care Diagnostics

Enabling rapid, quality results for critical decisions at the point of care.





Acute Care requires timely, decisive action, based on accurate diagnostic assessment. That's why thousands of hospitals rely on our Acute Care Diagnostics portfolio. Our integrative blood gas and whole blood hemostasis cartridge-based systems deliver fast, actionable results, allowing our customers can remain focused on patient care.

In 2021, we continued to grow our global market presence with extraordinary shipments of systems, particularly GEM® Premier™ 5000 blood gas systems, but also Hemochron™ and VerifyNow™ systems, as elective procedures resumed. Adoption of GEMweb® Plus Custom Connectivity.

Further, we expanded the controlled commercialization of the GEM Premier ChemSTAT® system around the world. We also initiated the controlled commercial release of the GEM Hemochron 100 whole blood testing system and the GEMweb Live data viewer.

### Giovanni Russi

COO, Hemostasis and Acute Care Diagnostics

Comprehensive and integrated line of whole blood diagnostic solutions designed to improve the quality of patient care and efficiency in hospital acute care settings.

## Innovation



### GEM® Premier™ 5000

GEM Premier 5000 blood gas testing system provides automated quality assurance with every whole blood sample. With next-generation Intelligent Quality Management (iQM2), featuring IntraSpect™ technology, potential errors are detected not only before and after, but also during sample analysis, along with real-time correction and documentation. The all-in-one GEM PAK cartridge only has to be changed once a month. So regardless of testing location or point-of-care operator, quality results and compliance are assured with every sample.

**Assuring quality before, during and after sample analysis—for improved patient care.**

# Autoimmunity

Shaping the future of autoimmune disease management by closing the seronegative gap.



**Roger Ingles**  
COO, Autoimmunity

In 2021, revenue increased by more than 20%, as physician office visits resumed, and undiagnosed patients were tested for autoimmune diseases with our products. The commercial expansion of the Aptiva® multi-analyte system and reagents into several key global markets was a significant accomplishment. The cornerstone for our future success, Aptiva offers the most comprehensive assay menu in autoimmunity testing, including more than 60 analytes in advanced stages of development, and over 15 unique and/or proprietary markers.

Key milestones achieved, enabling growth in 2021 and beyond, included 501(k) clearance for the Aptiva Celiac Disease IgA and IgG assays from the US FDA, as well as CE mark for the Aptiva CTD (connective tissue disease) Essential panel.

Innovation and market expansion, coupled with the continued success of our legacy product line, featuring BIO-FLASH®, ELISA and immunofluorescence assays (IFA), continue to solidify Werfen's leadership in the autoimmunity market.

## Innovation

### Aptiva®

Aptiva is a fully automated multi-analyte system that represents the next generation of high throughput instruments for the clinical laboratory.

Aptiva addresses many health economic shortcomings in the autoimmune laboratory. Existing systems provide a limited number of analytes that leave a significant seronegative gap found in many disease states. Aptiva will cover several autoimmune disease states and has over 60 analytes in various stages of advanced development.

**These analytes have the potential to help clinicians close the seronegative gap and improve diagnostic confidence.**





Autoimmune diseases affect approximately one in five people globally, while proper diagnosis for most patients requires up to five years and nearly five physicians. To help address this challenge, our broad menu of highly sensitive autoimmunity reagents allows clinicians to diagnose and treat patients rapidly, while automation of our instrumentation and digital solutions enables laboratories to operate more efficiently—ultimately reducing healthcare cost and enhancing patient care.



# Original Equipment Manufacturing (OEM)

Ranking among the top centers of excellence for immunoassay development and manufacturing in the Specialized Diagnostics industry.



**José Luis Zarroca**

COO, Original Equipment Manufacturing

In 2021, although the pandemic continued to present challenges, we were able to successfully manage increasing market demand and fulfill our partners' needs.

We are also pleased to have closed a new development and supply agreement with one of the major, global diagnostics players. This significant achievement positions us as a leading partner for OEM for immunoassays.

Additionally, we launched two new chemiluminiscent assays for a new platform for one of the top diagnostic worldwide suppliers. We also welcomed the first pre-market approval and three new products have been submitted to FDA for approval in the assays area.

Moreover, we validated more than 10 relevant biomaterials for chemiluminiscent reagents for the autoimmunity portfolio and for our OEM partners, consolidating our biotechnology expertise and services in the market.

As part of our quality culture, we delivered 178 quality training events, 244 continuous improvement projects and successfully passed multiple external audits of our ISO13485 / IVDR / MDSAP compliant quality system.





# Other businesses

## Clinical Chemistry

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

Clinical Chemistry offers easy-to-use clinical laboratory instrumentation and reagents for chemistry and pharma-toxicology laboratories. Our unique solutions are used to diagnose conditions, such as diabetes, as well as to identify drug abuse.

## Other Specialized Diagnostics products

In addition to our portfolio of proprietary Specialized Diagnostic products, some of our affiliates, mainly those in 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 deliver these 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.



## Clinical Software

With a solid foundation of talent, quality, and clinical expertise, we continue to be committed to developing and supporting safe, secure, efficient, and innovative clinical applications and laboratory instrumentation systems.

### 2021 Highlights

Clinical Software has once again achieved its main objectives, despite the challenges of working remotely and the transition to a hybrid remote/offsite working model. This we have done successfully and our close collaboration with the Development and QA/RA departments has remained crucial to the success of our projects.

Regarding the achievements and challenges that Clinical Software has significantly contributed towards, we would highlight the following:

- Specialized data managers and middleware solutions for Hemostasis, Acute Care Diagnostics, Autoimmunity and other clinical areas are key components in our strategy. Clinical Software has been and continues to be crucial in the development and evolution of these systems. Keeping these systems technologically up to date is a must, and during this year important advances have been made.
- Significant contribution to the development of next generation instrumentation projects, facilitating the achievement of planned milestones key to bringing products to market on time.
- The IT Support Services Center of Excellence has been consolidated under the leadership of Clinical Software
- A strong cybersecurity team has continued to evolve and grow, in close collaboration with Product Privacy and Security Office (PPSO). An internship program has been created in collaboration with local universities. The program allows the PPSO to identify, attract and grow young talent

In addition to these achievements, in 2021 we focused efforts on process harmonization, and agile software development methodology has become part of our DNA. We have also embraced DevOps methodologies to take us to the next level.



# Medical Devices

We distribute both our own and third-party medical devices such as disposables, solutions for wound care, devices for endovascular procedures and systems 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, pharmaceutical, chemical and agro-food industries.

## Medical Devices & Scientific Instrumentation Distribution

After a complex 2020, in 2021 our commercial activities continued to be affected by lockdowns and restrictions due to the pandemic. This mainly had an impact on the promotion and introduction of new product lines. Turnover increased slightly over 2020 figures, mainly led by sales of capital equipment and products related to surgical activity.

### 2021 Highlights

- Izasa Medical, thanks to its highly diverse portfolio, achieved growth of 5% over 2020, despite a reduction in demand for personal protective equipment which boosted sales in 2020, due to the pandemic.
- Izasa Scientific had an outstanding year, exceeding the 2020 results across almost all its business lines. The main growth driver was the private sector, thanks in large part to the new commercial strategy implemented in 2019, more oriented to the different needs of each of its target markets.
- MC Medical, continued expanding its installed base of ventilators for ICUs and inked a new partnership in the Orthopedics field with Syntellix.
- Nicolai continued expanding its presence in the gastrointestinal business while launching a new product line in the Interventional Cardiology field.

## Infusion Therapy

- Can Margarit, Spain – new facilities: Transfer to our new state-of-the-art facilities was completed. The facilities incorporate the latest technologies, expanded capacity and above all, superior quality.
- We obtained the coveted MDSAP Certification, which represents another step forward in our model of excellence.
- We relaunched our website, incorporating multiple functionalities and a new private area for our registered users.
- DOSI-FLOW® IV Flow Regulator manufacturing and sales exceeded 12 million units in a year, for the first time.



# R&D highlights

Our main objective remains unchanged — using R&D to drive even better results and to promote innovation in our areas of specialization to benefit the society we live in. More than 11% of our employees are engaged full-time in R&D and every year we invest more in this critical area. In 2021 we invested €111 million, a 5% increase over 2020.

At Werfen our passion for innovation starts with R&D. With many hospitals and laboratories around the world, using our diagnostics solutions, we understand the importance of our products in the delivery of the highest quality patient care. This inspires us to continuously improve our systems, reagents and data management solutions, as well as innovating new ones, to expand our impact on diagnostic testing in hospitals around the world.

Our teams are comprised of highly skilled engineers, scientists and expert project managers. To maximize collaboration and efficiency, the majority of our R&D is conducted completely internally. And leveraging their close proximity to our technology centers — they optimize product design and efficiency together.

Our approach to R&D is multifaceted, encompassing specialized laboratories and areas of expertise throughout our innovation process. Here are some highlights.

\*Not 510-k-cleared by the US FDA. Not available in all countries.







### The Model Shop

Located steps away from our instrument designers, our unique model shop creates product prototypes internally, quickly and efficiently. A variety of potential materials are available for experimentation. After rigorous testing, input is applied to create modified prototypes, and the process continues until the ideal form and materials are identified.



### Hardware Integration Laboratory

System designs are evaluated in our Hardware Integration Laboratory, where we ensure they meet the highest standards. Prototypes are tested and exposed to a variety of conditions, including the thermal testing chamber, to ensure quality performance in any environment.



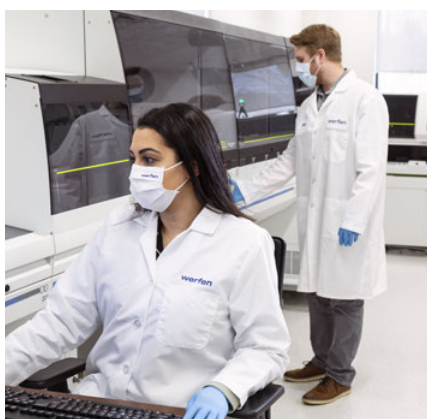
### Software Testing Laboratory

Integral to our solutions is software designed specifically for each hemostasis system, with customer needs and usability at its core. Hemostasis software is tested with the same rigor applied to hardware and includes extensive usability research with our customers. This allows us to develop reliable and standardized solutions with user-friendly interfaces and features.



### Analytical Laboratories – Hemostasis and Acute Care Diagnostics

We develop instruments and a broad menu of assays, for a complete diagnostic solution. In our analytical laboratories, our highly skilled, quality-driven and metric-focused teams meticulously verify their combined performance. This allows us to offer our customers a family of products that seamlessly work together to produce the highest quality test results, for the highest quality patient care.



### HemoCell® Lab

For mid- to the high-volume hemostasis laboratories, we offer the industry-leading HemoCell Specialized Lab Automation, a unique work cell, customized to the individual needs and footprints of each lab, and designed for testing efficiency. Here in our HemoCell laboratory, we test methods for continuous improvement, often inspired by customer feedback. Accessories, such as the status-indicator light pole and rinse manifold, are examples of this, arising from our in-depth R&D process.



### Early-Life Monitoring and Systems Engineering

The R&D process doesn't end when a product goes to market. Early-life monitoring and tests by systems engineering of our on-market products can detect performance trends. Customer feedback is crucial to the product life cycle management of all our instruments, software and reagents allowing us to continuously improve the quality of our products.



# Commercial Operations

Brian P. Durkin is our new head of global Commercial Operations and under his leadership, and with the support of six regional vice presidents, he provides a deeper understanding of market trends and opportunities; the identification of synergies and best practices; and the ability to leverage resources and operational efficiencies.



**Brian P. Durkin**  
Chief Commercial Officer

## North America

2021 was a historic year, in many ways. We consolidated Commercial Operations in North America. The customer and market response to the July announcement was extremely positive—a resounding success.

While the commercial synergies of this alignment are clearly positive, the new structure presented unique challenges, in addition to those associated with managing through the ongoing COVID pandemic. Nevertheless, the Commercial Operations organization in North America displayed ongoing resilience and achieved extraordinarily positive results. Despite COVID restrictions at customer sites, our Service, Support and Applications groups exceeded all customer field requirements, validated by extremely positive customer-survey results. Through a combination of remote and on-site meetings with customers and prospects, our sales team delivered historically high instrument and reagent sales in all business lines, including

Hemostasis, Acute Care Diagnostics and Autoimmunity. Ultimately, the combination of best-in-market products, our highly trained and engaged commercial team, and continued investment in process efficiencies led to our collective success in 2021.

## Europe

The European team had another successful year in 2021, reporting strong results overall and for each business unit. Our solutions continued to prove critical to the care of COVID patients in 2021, especially given the performance of our best-in-class solutions for D-Dimer and GEM Premier throughout Europe and PCR testing in Spain and Portugal. Additionally, other businesses effected by the pandemic in 2020 delivered strong performances, such as Autoimmune Diagnostics and Whole Blood Hemostasis testing.

It is worth highlighting that even in the face of pandemic in 2021, the team remained vigilant, adapting our go-to-market strategies and customer support approach to ensure sustained growth and customer satisfaction well into the future. Perhaps more impressive is the positive, can-do attitude of our team that results in our customers truly recognizing the value that our people and products deliver to healthcare systems throughout Europe.

## EEMEA, LATAM and APAC

Our teams in EEMEA, LATAM and APAC continued to navigate the challenges brought by the pandemic, aiming to closely collaborate with customers and users, and investing time and effort to develop educational content for laboratory personnel and clinicians. Here we would highlight how our solutions provided support in diagnosing and treating COVID-19 patients.

With limited opportunities to engage in face-to-face activities with customers and prospects, we developed and arranged an array of digital and virtual events that were greatly appreciated by all our stakeholders.

## China

In 2021, China's Zero-COVID strategy has been the norm, closing much of the country off from the rest of the world and making travel in China more challenging. However, there has been much less impact in hospital activity compared with 2020. We achieved our sales objective across all of our lines and outperformed our key competitors.

Capitalizing on the online experiences we have been developing since the onset of the pandemic, we carried out amazingly successful online/offline forums, attracting thousands of attendees and garnered very positive feedback. Another important focus has been to continue growing our ValueSelling capabilities, from both marketing and sales standpoints.

Werfen Voices, our global employee engagement survey, reported very strong numbers across the board – highlighting that despite the pandemic, our employees feel satisfied, are happy and optimistic about the future.

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# Commercial Operations Organization

The regions, which include dedicated country-specific teams, are organized into six regions – North America, Europe, China, Asia Pacific, EEMEA and Latin America.



**Bill Crandell**

VP Commercial Operations  
North America



**Ted Maione**

VP Commercial Operations Europe



**Pepe Zamora**

VP Commercial Operations EEMEA



**Luis Faus**

VP Commercial Operations  
Latin America



**Jaume Serra**

VP Commercial Operations APAC



**Gilles Castera**

VP Commercial Operations China

# Locations

- Headquarters
- Technology Centers
- Medical Device Companies
- Affiliates

## Headquarters

*Barcelona, Spain*

## Hemostasis and Acute Care Diagnostics

**Headquarters and Technology Center:**  
*Bedford, MA, USA*

**Technology Centers:**

Hemostasis and Blood Gas Reagents  
*Orangeburg, NY, USA*

Whole Blood Hemostasis  
*San Diego, CA, USA*

Patient Blood Management  
*Munich, Germany*

## Autoimmunity

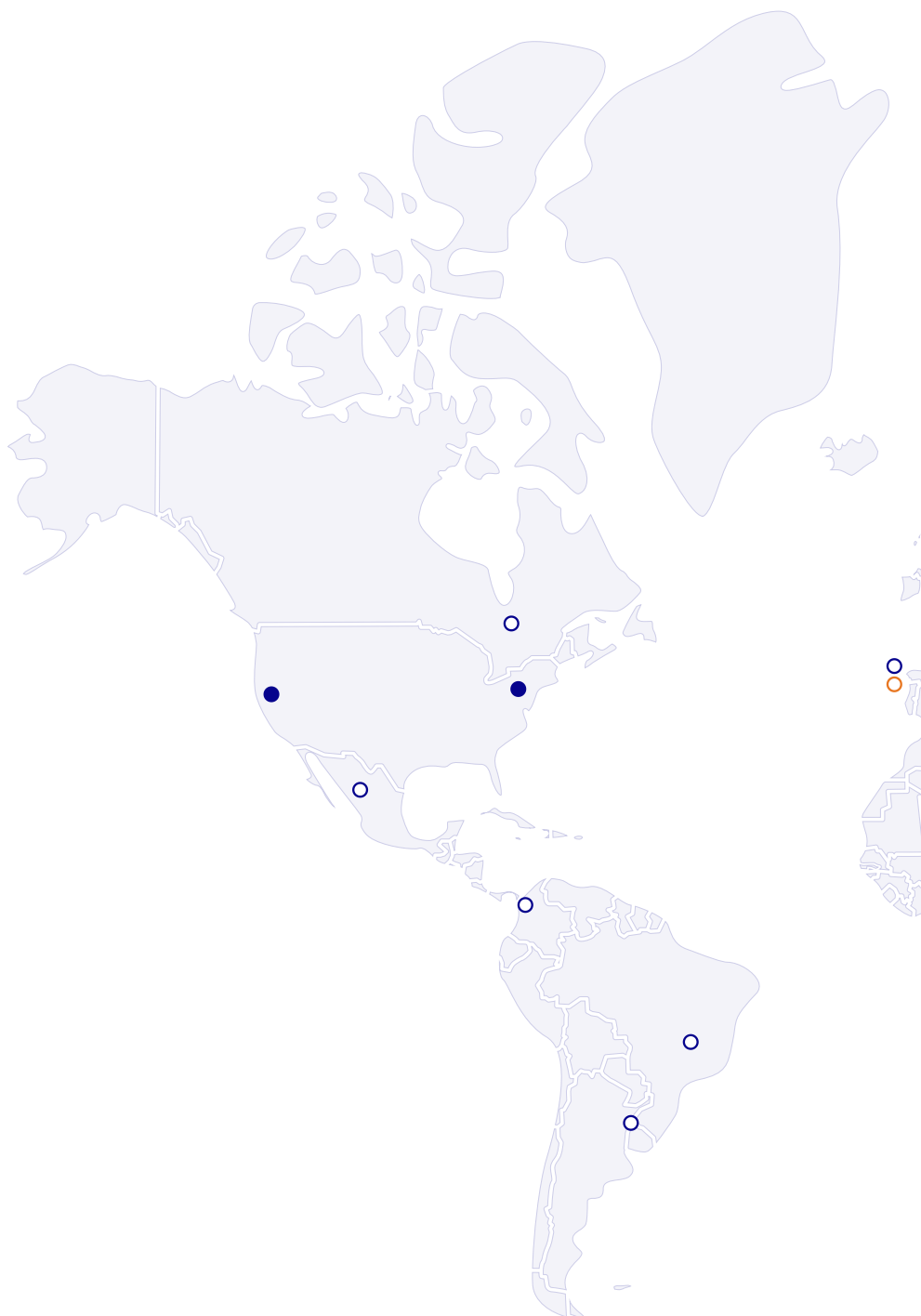
**Headquarters and Technology Center:**  
*San Diego, CA, USA*

## Original Equipment Manufacturing

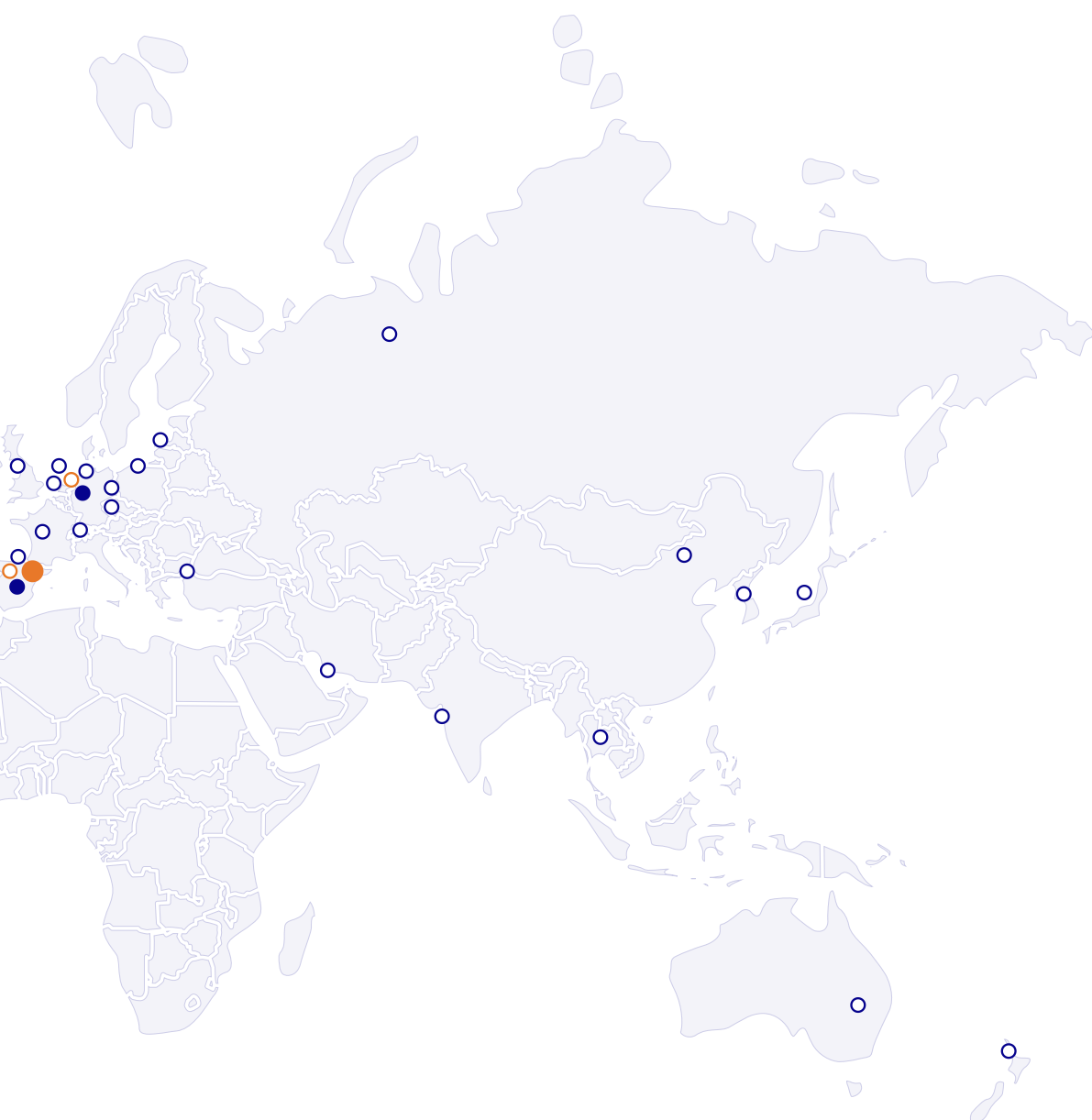
**Technology Center:**  
*Barcelona, Spain*

## Medical Device Companies

Izasa Medical  
Izasa Scientific  
Leventon  
MC Medical  
Nicolai



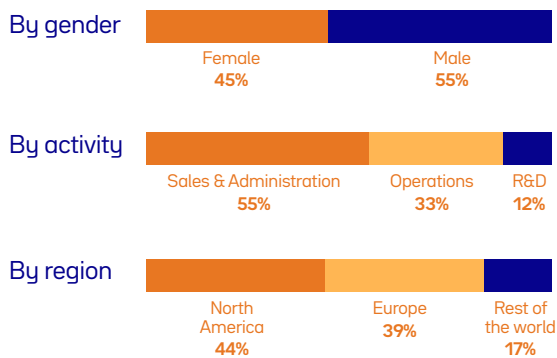




## Affiliates

Australia	Mexico
Austria	Netherlands
Belgium	New Zealand
Brazil	Poland
Canada	Portugal
China	Russia
Colombia	South Korea
Czech Republic	Spain
France	Thailand
Germany	Turkey
India	UAE
Italy	UK
Japan	Uruguay
Lithuania	

**5,643** employees



NOTE: Percentages may not add up due to rounding.

# 05

## Governance

Werfen is committed to the highest international standards of corporate governance and this is reinforced in its structure, processes and rules as outlined in this section of the Annual Review.





# Board of Directors

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



**Marc Rubiralta**  
President

Bachelor of Business Administration;  
MBA  
• 13 years at Werfen (2009 - present);  
• President of Werfen since January  
2019



**Carlos Pascual**  
CEO

Bachelor of Law; MBA  
• 34 years at Werfen



**José Luis Guerrero**  
CFO

Bachelor of Business Administration;  
MBA  
• 20 years at Werfen



**Jordi Rubiralta**  
Director

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



**José Luis Rubiralta**  
Director

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



**Xavier Rubiralta**  
Director

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



**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**  
Secretary non-Director

Corporate Lawyer

- Expert in the field of Law and Family Business

## Committees

### Executive Committee

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

The Executive Committee is responsible for the day-to-day management of the Company, in line with the strategic guidelines defined by the Board of Directors, and the powers delegated also by the Board of Directors.

### Audit and Control Committee

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

This committee reports directly to the 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.

### Appointments and Remuneration Committee

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

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.

### Strategy Committee

Marc Rubiralta, **Chairman**  
Jordi Rubiralta, **Member**  
Carlos Pascual, **Member**  
José Luis Guerrero, **Member**  
Germán Castejón, **Member**  
Luis Cantarell, **Member**

The primary objective of the Strategy Committee is to assist and advise the Board of Directors of the Company in developing and implementing the Company's long-term strategic plans.

# Compliance

Compliance Officer, Albert Garicano, and our local compliance officers are committed to ensuring that our Code of Ethics is consistently complied with worldwide.



**Albert Garicano**  
Compliance Officer

Werfen's Purpose is to contribute to the advancement of patient care around the world through innovative Specialized Diagnostics. We accomplish it through affiliates, which foster and promote Werfen's Values. However, in many other geographic areas we operate through a wide network of business partners. Our responsibility and commitment to the highest ethical standards does not end with our employees, but also includes those who work on our behalf.

For this reason, Werfen has made great efforts in recent years to develop its compliance program, especially in the field of third-party risk management. In this regard, in 2021 Werfen launched the Business Partner Compliance Audit Program, which complements the previously implemented Business Partner Due Diligence and Compliance Training programs. This initiative, although in its initial phase, completes all the stages of the third-party risk management process and raises the level of the Werfen Compliance Program to the best practices in the market, ensuring compliance with complex international law requirements.





# Quality Assurance and Regulatory Affairs

## Our Quality Policy

Reaching for a higher standard



**Marc Bellosta**

Vice President, Quality Assurance & Regulatory Affairs, and Sustainability

All our systems, reagents and data management solutions must meet our exceptional standards. We always go the extra mile – across all business lines and geographic areas – making sure we deliver only the best. Werfen has 56 ISO certificates – an indication of our constant commitment to quality, sustainability and our customers.

## QA/RA Mission Statement

**Facilitate innovation by providing a framework that ensures high product and service quality, while meeting legal and regulatory requirements through collaboration with all interested parties, balancing risks with benefits.**





## ISO certificates

The International Organization for Standardization (ISO) issues ISO Certificates to ensure the safety, reliability and quality of products and services.

### ISO 9001

Ensures that the organization provides products and services that consistently meet customer and regulatory requirements, and that the organization consistently aims to enhance customer satisfaction.

### ISO 13485

Ensures that the organization provides medical devices and related services that consistently meet customer and regulatory requirements. All Werfen manufacturing sites are certified with this standard.

### ISO 14001

Ensures that the organization strives to manage its environmental responsibilities in a systematic manner and in compliance with international and local environmental regulations.

### ISO 27001

It ensures that the organization safeguards the security of assets such as financial information, intellectual property, employee details or information entrusted to you by third parties.



# 06

## Sustainability

In 2021 we dialed up our sustainability efforts. We continued to encourage all local action and initiatives, while also implementing corporate strategies and governance.





# Towards a more sustainable future

## The UN Global Compact

**In 2020, Werfen officially became a signatory member of the UN Global Compact.**

The UN declared this decade a decade of action to deliver its Sustainable Development Goals (SDGs) by 2030. As a leader in our industry, we responded to this call.

Werfen supports the UN Global Compact as an integral part of our company values in favor of world development and as a differentiator for our customers, employees and partners.



## We commit to the UN Social Development Goals (SDGs)

**The UN SDGs establish a framework for building a more inclusive and sustainable world. They also provide Werfen with the opportunity to deepen our collaboration with our stakeholders.**

We are uniquely positioned to achieve the SDGs by:

- Proactively managing our internal operations and supply chain;
- Launching Environmental Social Governance (ESG) programs;
- Practicing diversity and inclusion;
- Offering products, solutions, systems and services to our customers.

### Our stakeholders

Shareholders, governance bodies, financial community, personnel, customers, distribution partners and suppliers, regulatory bodies, health competent authorities, notification/certification bodies, communities where we operate, national/international associations, patients, planet, employment candidates.

In 2021 we performed a new Materiality Assessment to identify our stakeholders and their needs.

### Prioritizing the SDGs

All 17 UN SDGs are important to Werfen and we prioritize them in line with the expectations of our stakeholders.

On the next page are the 15 SDGs we worked toward in 2021.





## Ten Principles of the UN Global Compact

We adhere to the Ten Principles of the UN Global Compact and commit to implementing them and making them part of our strategic vision, organizational culture and day-to-day operations.

### Human Rights

#### Principle 1:

Businesses should support and respect the protection of internationally proclaimed human rights.

#### Principle 2:

Make sure that they are not complicit in human rights abuses.

### Labor

#### Principle 3:

Businesses should uphold the freedom of association and the effective recognition of the right to collective bargaining.

#### Principle 4:

The elimination of all forms of forced and compulsory labor.

#### Principle 5:

The effective abolition of child labor.

#### Principle 6:

The elimination of discrimination in respect of employment and occupation.

### Environment

#### Principle 7:

Businesses should support a precautionary approach to environmental challenges.

#### Principle 8:

Undertake initiatives to promote greater environmental responsibility.

#### Principle 9:

Encourage the development and diffusion of environmentally friendly technologies.

### Anti-corruption

#### Principle 10:

Businesses should work against corruption in all its forms, including extortion and bribery.

# 2021

## Turning up the volume

In 2021 we dialed up our sustainability efforts. We continued to encourage all local action and initiatives, while also implementing corporate strategies and governance.



With each of the UN SDGs in mind, we set out specific objectives for 2021 and planned actions to meet them.

Our 2021 sustainability report details our achievements for each of our objectives, with a deep dive into all our ESG initiatives around the world.

In 2021 we developed a strategic sustainability plan with initiatives designed to integrate social, environmental and economic considerations into our core values, our culture and our day-to-day operations. A head of corporate sustainability was appointed to lead and develop this program, and contribute to the UN's broader development goals and SDGs.

This is the year we pulled out the stops and ramped up communication to embed sustainability internally under the premise of transparency and accountability.

In addition to continuing to dedicate substantial efforts to our social actions, in 2021 we significantly increased our environmental projects, with a focus on minimizing the global impact of our CO<sub>2</sub> emissions. In fact, we exceeded our goal and achieved 80% of clean energies—a momentous improvement from the 41% in 2020. This places us in a good position for carbon neutrality.



### Sustainability Report

[Go here](#) to read or download our 2021 Sustainability Report.



### Sustainability Policy

In 2021, we launched a [Sustainability Policy](#) which sets out the principles that govern our business operations.



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# The 3 Ps of sustainability

We are focused on three areas, all equally important and interconnected:



PEOPLE

## Social equality

Our commitment to human rights, security, equality, inclusion and diversity in all respects.



PLANET

## Environmental protection

Our impact on the environment including CO<sub>2</sub> emissions, waste management or biodiversity.



PROSPERITY

## Economic development

Our economic growth and our efficiency using resources like energy or materials.





# 07

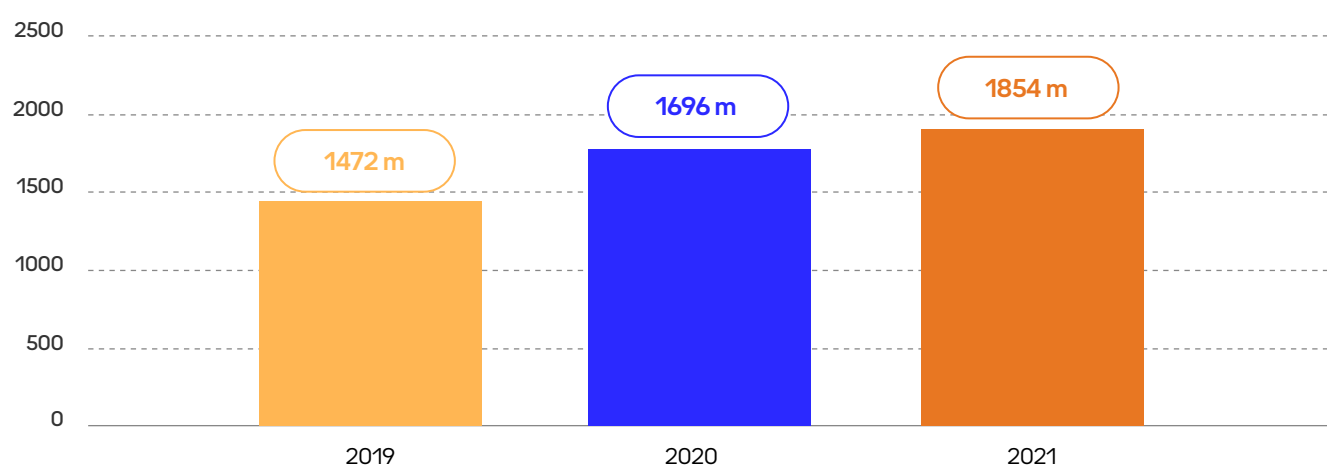
## Key financial data

Sales up by 9.3% to €1.854 billion in 2021. Growth was driven by all product lines, in all geographic regions which posted double digit growth.

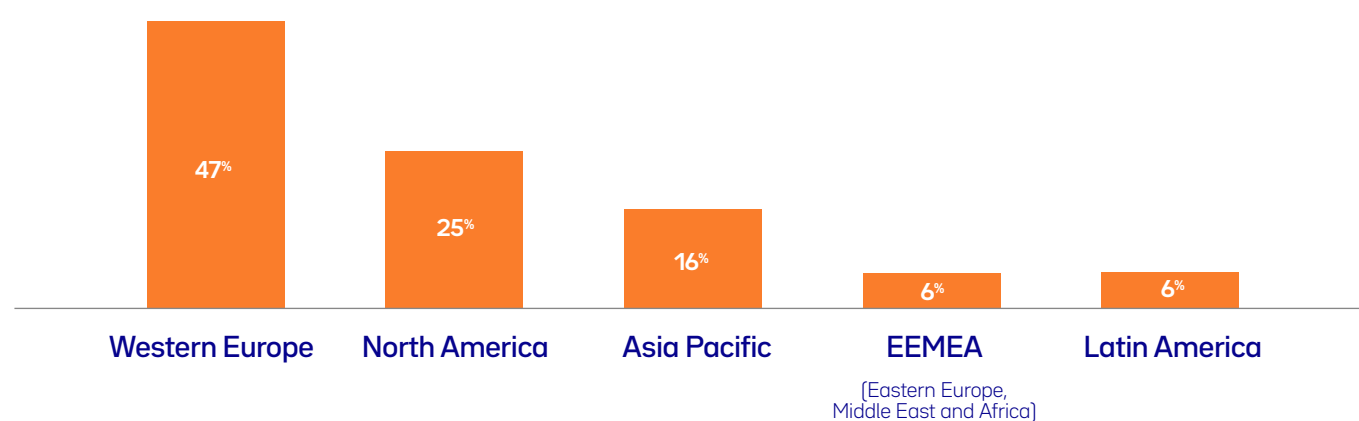


# Key financial data

## Sales 2019-2021 [€ millions]



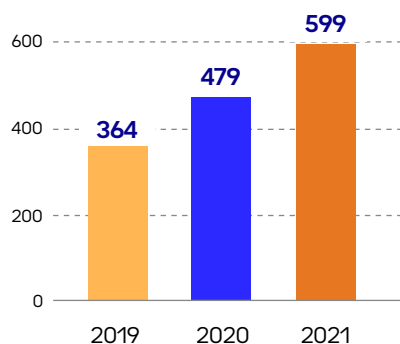
## Sales by region [% of Sales]



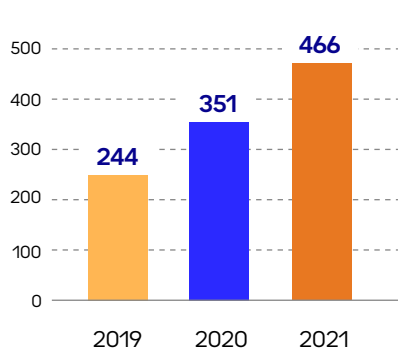


## Key figures, 2019-2021 (€ millions)

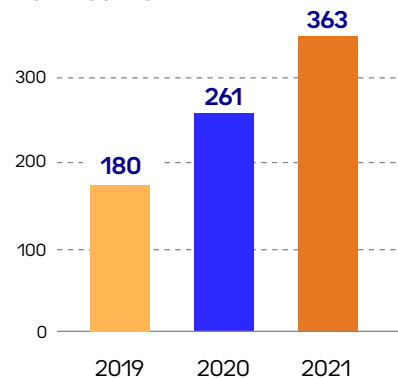
### EBITDA



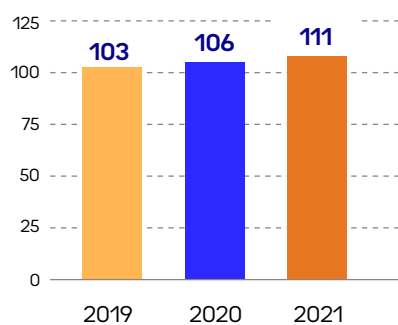
### Operating Income



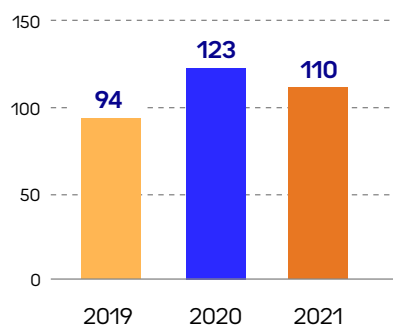
### Net Income



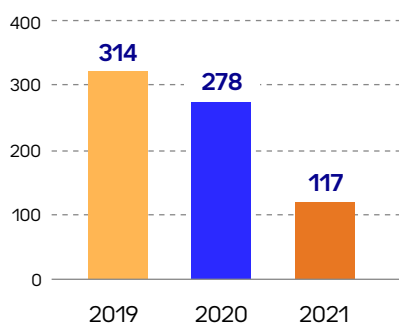
### R&D expense



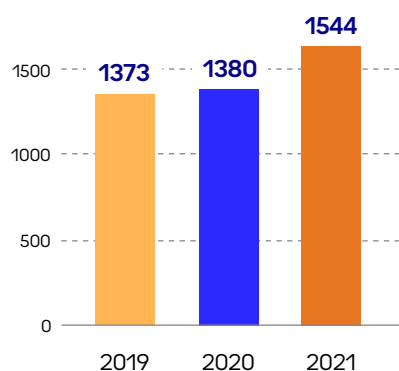
### CAPEX



### Net Debt



### Net Equity





## Werfen Headquarters

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+34 934 010 101

[werfen.com](http://werfen.com)