



Annual Report 2017





Everything we do, we do at the service
of patients and the healthcare community.



Annual Report 2017



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OVERVIEW

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President's Letter

Dear all,

2017 was an exciting and rewarding year. We continue to lead in *In Vitro* Diagnostics (IVD), specifically in Hemostasis, Acute Care Diagnostics, and Autoimmunity, complemented by our Medical Devices business. **Our consolidated sales were 1,337 million euros, representing steady growth of 4.6% against 2016 in constant currency, and a 13.3% increase including recent acquisitions.** We achieved our objectives and performed well in our key markets, especially in China where our growth was well above expectations. **All other geographical areas also experienced growth** compared to 2016—an achievement in today's constantly changing healthcare landscape.

Our industry is changing, and we need to be able to serve our customers, with a focus on the added value we deliver them each and every day. We want to highlight our broader contribution to healthcare; the way we help health practitioners make quicker, more accurate decisions, while also helping to reduce unnecessary costs. All with the ultimate goal of enhancing the quality of patient care and the patient experience.

We are committed to creating more comprehensive, tailored solutions that can help patients around the world live healthier and better lives. To demonstrate this commitment, we increased our investment in R&D by 21% in 2017.



Jordi Rubiralta

The Werfen community consists of around 30 affiliates, distributors, and our companies—Instrumentation Laboratory, Inova Diagnostics, Biokit, and Leventon. It now also includes Accriva Diagnostics and Tem that were acquired for close to 500M€ at the beginning of 2017 and in late 2016 respectively, and together we are stronger than ever. The integration of these two companies into Instrumentation Laboratory has reinforced our position in the market, driven our growth, and expanded the breadth of our offering throughout the hospital in Patient Blood Management and Whole Blood Hemostasis. As a result, our Critical Care business line has evolved into the broader Acute Care Diagnostics business line. Other significant milestones include opening a new affiliate in Colombia, completing the move to the new Biokit Technology Center located near Barcelona (Spain), opening new logistics centers in Uruguay and Brazil, and the official start-up of operations at the new logistics center for Spain and Portugal, located in Cuenca (Spain).

"We are committed to creating more comprehensive, tailored solutions that can help patients around the world live healthier and better lives."

Last year we celebrated our 50th anniversary as a company—a milestone that was especially meaningful to me as a way to pay homage to my father, and our founder, José María Rubiralta, who had the vision and courage to undertake this journey that has led us to where we are today: global leaders in our main areas of expertise. Many commemorative events were organized around the world, all with the common goal of sharing how proud we feel to belong to the growing Werfen community. **Today, the Werfen team is made up of over 5,000 talented and passionate professionals**, 41% of whom are now located in the United States, based mainly in Bedford (MA), Orangeburg (NY) and San Diego (CA).

We also carried out activities to better position ourselves in the market. We launched brand new websites offering easy access to key information that benefits customers, prospects, and employees. This has strengthened our presence in the digital arena and helped us optimize our brand awareness. In terms of reinforcing our values, we have implemented various initiatives to foster a culture of participation and employee engagement. We achieved a 93.4% participation rate for our first ever organization-wide engagement survey, with very positive results. Therefore, we feel it is both an honor and our responsibility to continue offering a work environment where people can grow both professionally and

personally. We also emphasized the importance of Compliance, and doing business in an ethical and sustainable way, by organizing several initiatives, including training sessions, for all employees across the organization.

Moving forward, we want to maintain our global leadership in IVD, continuing the integration of Tem and Accriva Diagnostics solutions into our offering and thereby maximizing value creation for our stakeholders. In order to achieve our goals, we are committed to hiring, motivating, and retaining the best talent, because our people are definitely our biggest asset and our number one competitive advantage. Our team is driven by excellence and a passion for innovation, and guided by integrity and humility. We work together as a team to be able to offer our customers the best solutions and, ultimately, make our contribution to a better world.

Thank you for your continued trust in Werfen.

Sincerely,



Jordi Rubiralta
President

Overview

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.



Number of Employees¹

	2017	2016
Employees	4,938	4,388



¹ Average



Activity

	2017	2016
Sales & Administration	54%	57%
R&D	11%	11%
Operations	35%	32%

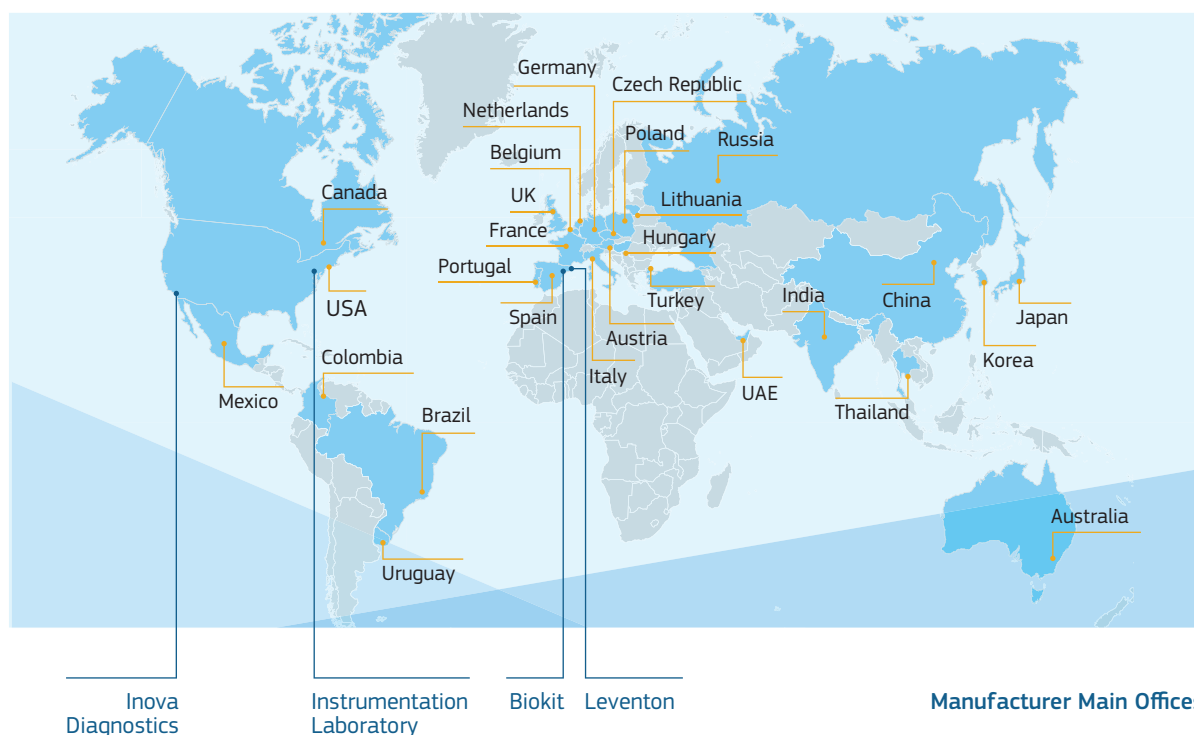


Geographical Area

	2017	2016
Europe	45%	49%
North America	41%	36%
Rest of the World	14%	15%

Locations

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





In Vitro Diagnostics (IVD)

Non-invasive tests performed on biological samples such as blood, urine, or tissue, to diagnose, monitor, or rule out a disease.

In vitro diagnostic products include e.g. reagents and systems. These products are used in the collection, preparation, and examination of specimens taken from the human body.

Source: US Food and Drug Administration, 2017.



Medical Devices

Instruments, machines, appliances .../... intended to be used for diagnosis, prevention, monitoring, treatment or alleviation of a disease or injury.

Source: World Health Organization, 2017.

Our main business is IVD, and we also work in the Medical Devices field.

IVD

- Hemostasis
- Acute Care Diagnostics
- Autoimmunity
- Original Equipment Manufacturing (OEM)
- Clinical Software
- Clinical Chemistry
- Infectious Disease Serology

Medical Devices

- Infusion Therapy
- Medical Devices & Scientific Instrumentation Distribution



Corporate



- Headquarters in Barcelona (Spain)

IVD

Hemostasis
Acute Care Diagnostics
Clinical Chemistry



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)

Autoimmunity



A Werfen Company

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

OEM
Infectious Disease Serology

Clinical Software
Affiliates



A Werfen Company



Diagnostic Solutions for Life

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

Medical Devices

Infusion Therapy



A Werfen Company

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

Medical Devices & Scientific Instrumentation Distribution



A Werfen Company



A Werfen Company



A Werfen Company



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A Werfen Company



A Werfen Company



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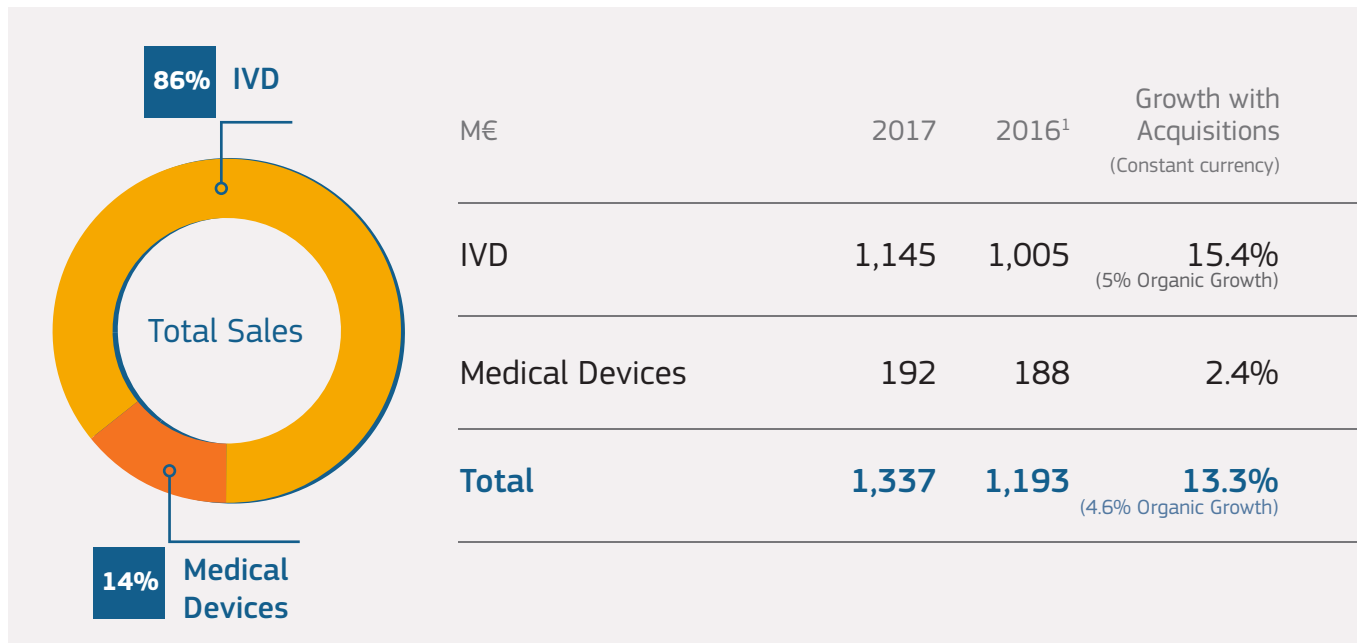
A man with short dark hair and a beard, wearing a dark polo shirt and light-colored trousers, is sitting on a modern-style chair. He is looking down at several sheets of paper scattered on the floor in front of him. The background is a plain, light-colored wall.

PERFORMANCE

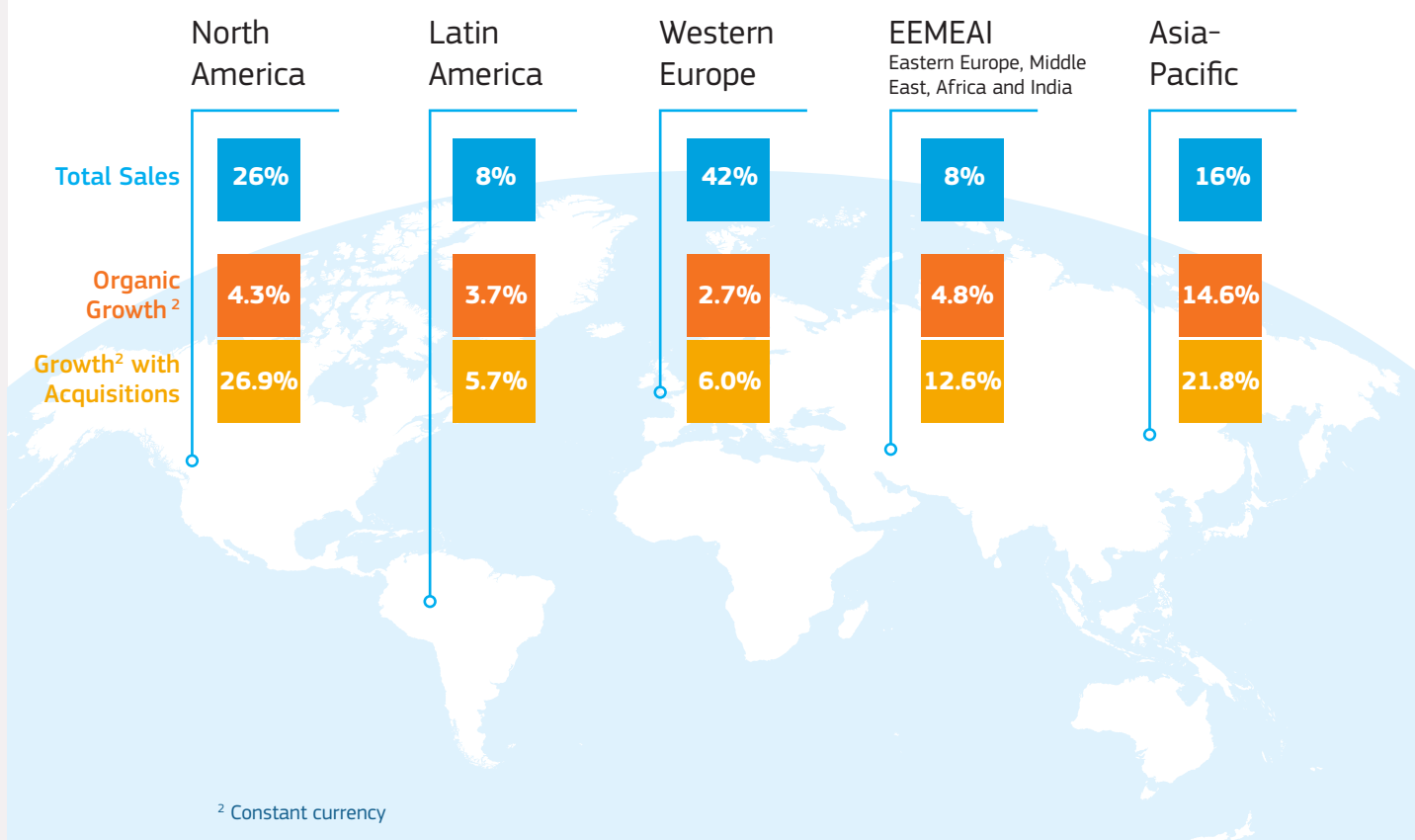
Financial Results
Affiliates of the Year
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Financial Results

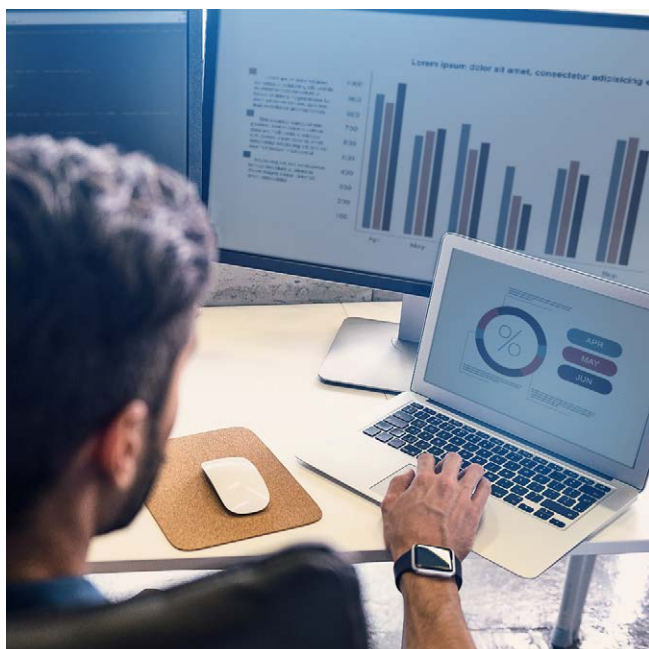
Sales in 2017 reached **1,337 million euros**, representing **13.3%** growth over 2016 in constant currency terms. The acquisition of Tem and Accriva Diagnostics had a positive effect on our financial results, while the depreciation of the Chinese yuan, the pound sterling, and the Mexican peso, against the euro had a negative impact. Our **organic growth**, excluding acquisitions, was **4.6%** in constant currency.



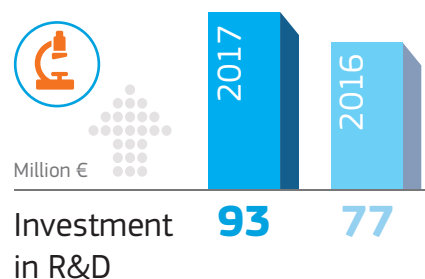
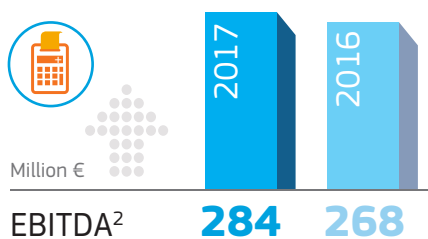
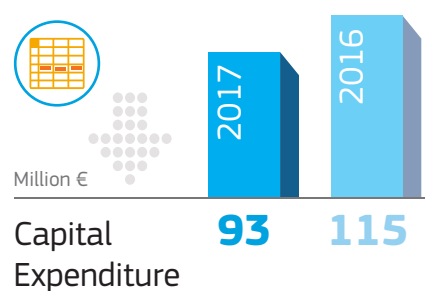
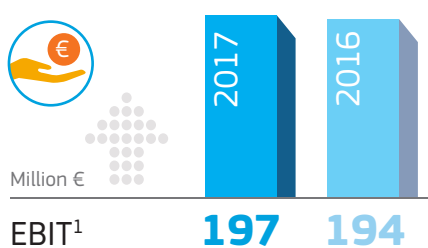
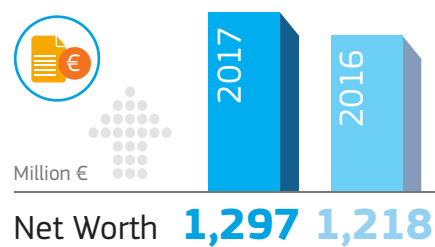
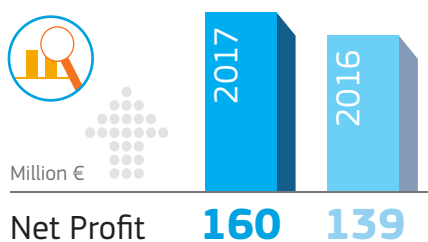
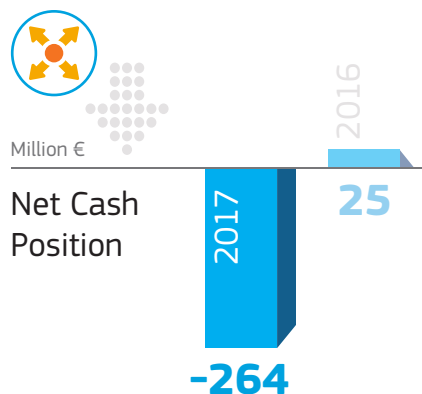
¹ Restated results



² Constant currency



Our consolidated sales amounted to 1,337 million euros and we invested 93 million euros in R&D in 2017.



¹ Earnings before Interest and Taxes.

² Earnings before Interest, Taxes, Depreciation and Amortization.

Affiliates of the Year

We achieved excellent results in several markets, such as China and Brazil, in 2017. We also opened a new affiliate in Colombia.

Werfen in China



Employees of Werfen in China

Highlights of 2017

China has continued its steady growth in 2017, with a 21% increase in sales over 2016. Hemostasis sales rose by 24%, Acute Care Diagnostics sales by 13%, and Autoimmunity sales by 90%.

Outlook for 2018

The outlook for China in 2018 is optimistic and ambitious. Ongoing and continuous training of our team and distributors will be the key driver of business, and solutions such as our ACL TOP® Family 50 Series will be introduced to the market. We believe that with best-in-class products, clear strategies, and value selling capabilities, we can make the most of the opportunities in the Chinese market.

Best-in-class products, clear strategies, and value selling capabilities will be key for our growth moving forward.

Werfen in Brazil



Werfen Latin America Convention

Highlights of 2017

Brazil increased sales by almost 24% in 2017, achieving some of the highest growth across all our affiliates. The business lines leading this expansion were Autoimmunity, with a 17% increase, and Hemostasis, with a 15% increase. In order to achieve these great results, Brazil used a value selling strategy focused on the biggest players in the market.

Outlook for 2018

In 2018, the target is to continue growing above the market rate and to expand our business.

Our Newest Affiliate

Werfen in Colombia

The IVD market in Colombia is currently experiencing double-digit growth, mainly due to the country's provision of universal health coverage and the equity of its various benefit plans. Werfen launched direct operations in Colombia in April 2017, focusing on the Hemostasis and Acute Care Diagnostics business lines.

Moving forward, Colombia will be aligned with corporate value selling objectives and focus on high-end penetration in both the Hemostasis and Acute Care Diagnostics markets, positioning Werfen as the company with the greatest added value in our specific areas of expertise. The integration of Accriva Diagnostics and Tem is fundamental to achieving these objectives.



Werfen Team in Colombia

In Vitro Diagnostics

Every day, laboratories around the world use Werfen reagents and systems to test more than 1.5 million patient samples.

***In vitro* diagnostic (IVD) testing impacts approximately 65% of all medical decisions.¹**

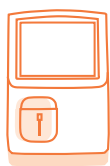
IVD testing is used to support the diagnosis, monitoring, and treatment of acute and chronic clinical conditions. At Werfen, we are dedicated to developing, manufacturing, and distributing IVD testing systems, reagents, controls, and data management software. Our three main areas of expertise within IVD are: Hemostasis, Acute Care Diagnostics and Autoimmunity.

Our solutions are used in hospital and commercial laboratories and in hospital acute care settings—Emergency Departments, Intensive Care Units, Operating Rooms, Cardiac Catheterization Labs and Interventional Neuroradiology Suites—by healthcare providers, from laboratorians and pathologists to respiratory specialists, surgeons, anesthesiologists, and more.

The quality of the analysis and timely reporting of results impact the care and treatment of each patient tested. By eliminating risks and reducing the possibility of medical errors, we are enhancing the quality of patient care and contributing to society, one patient at a time. This is our core business, our passion, and our expertise.



1 Patient Sample



2 Diagnostic Testing



3 Test Results Reporting



4 Diagnosis, Monitoring, Treatment



¹ Source: European Diagnostic Manufacturers Association, 2017.

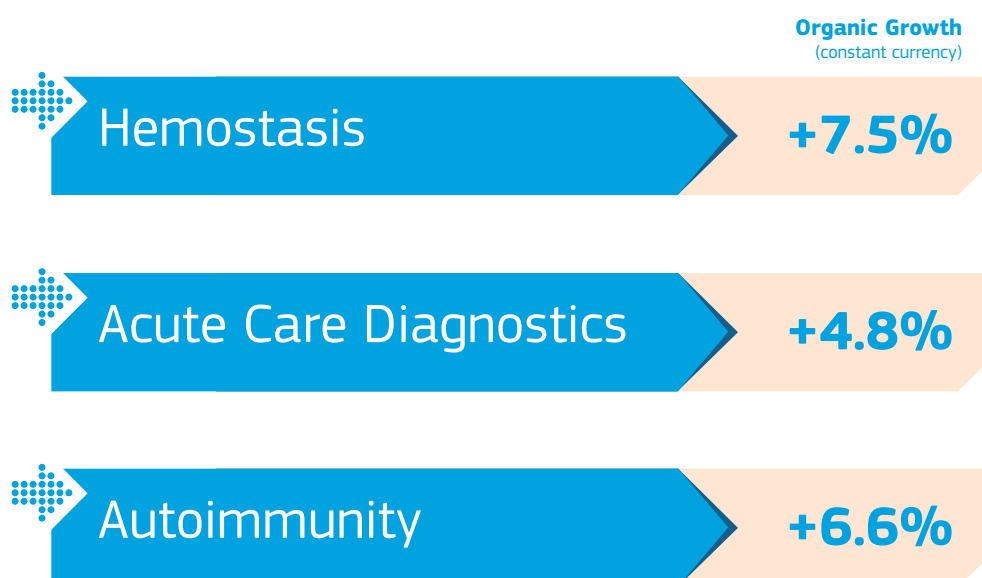
In vitro diagnostic (IVD) testing impacts approximately 65% of all medical decisions.¹



We operate in a highly regulated environment, where it is essential to meet or exceed the rigorous quality standards set by regulatory bodies around the world. We develop and manufacture our products for reliability, consistency and quality, and we offer first-in-class, tailored service and customer support. Healthcare providers—our customers—strive to deliver excellent patient care and patient satisfaction, and to control healthcare costs, and we are passionate about, and committed to, helping them achieve these objectives.

In 2017, IVD sales reached 1,145 million euros. This represents 86% of total revenue for Werfen.

Our Hemostasis business line grew above market in 2017, solidifying our #1 position globally with an estimated market share of 28%. Within Acute Care Diagnostics, our Blood Gas business line is positioned to achieve an 18% market share.² Our Autoimmunity business line achieved a 21% market share in 2016.



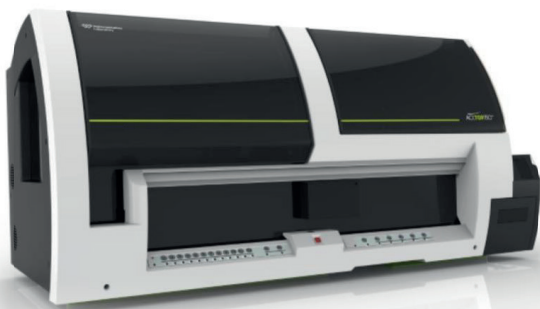
² Awaiting external reports to validate market share for 2017.

Hemostasis

Hemostasis innovation is here

Our Hemostasis business line, from our company Instrumentation Laboratory, is comprised of systems, reagents, controls, and data management solutions to diagnose and guide treatment of thrombotic and bleeding disorders. Ultimately, our Hemostasis portfolio helps improve the quality of patient care, lower overall costs, and ensure regulatory compliance in the clinical laboratory.

We offer a comprehensive line of intuitive, reliable, and intelligent products, including the industry-leading ACL TOP® Hemostasis Testing Systems, HemoCell™ Specialized Lab Automation, HemosIL® Assays, and HemoHub™ Intelligent Data Manager. We are dedicated to supporting healthcare professionals, and our Hemostasis solutions are designed to meet the needs of large laboratory networks and small hospitals alike.



ACL TOP 750 CTS



HemosIL® assays

New Products & Highlights of 2017

- **HemosIL AcuStar HIT-IgG_(PF4-H)** assay and controls, developed by Biokit, have received FDA 510(k) clearance in the USA. This is the first on-demand, fully automated, chemiluminescent reagent in a Hemostasis testing system for the qualitative detection of platelet factor 4 (PF4)-heparin complex IgG antibodies associated with Heparin-Induced Thrombocytopenia (HIT).
- New and important functionalities for **HemoHub Intelligent Data Manager** have been introduced, enabling advanced integration of ACL TOP Family 50 Series systems and HemoCell Specialized Lab Automation, as well as connectivity to ROTEM delta and sigma systems.
- **HemoCell Specialized Lab Automation** expanded into key markets around the world. The world's first lab automation workcell designed specifically for Hemostasis testing, HemoCell provides the benefits of specialized Hemostasis testing, while enhancing efficiency through automation.

"HemosIL HIT-Ab_(PF4-H) is a rapid, on-demand, fully automated laboratory assay for the detection of antibodies that cause heparin-induced thrombocytopenia (HIT). HIT is a serious complication of heparin therapy, paradoxically leading to high risk of life-threatening thrombosis. Rapid HemosIL HIT-Ab_(PF4-H) test results help guide appropriate patient treatment, thus contributing to cost control and improved care."

Theodore (Ted) Warkentin, MD, FRCP(C), FACP

Professor, Dept. of Pathology and Molecular Medicine, and Dept. of Medicine
McMaster University, Hamilton, Canada

- HemoCell Specialized Lab Automation presented for the first time at the **International Society on Thrombosis and Hemostasis (ISTH) Congress** in Berlin, Germany, in July. Other products on display for the first time at the ISTH booth included: ROTEM® sigma viscoelastic testing system, Hemochron™ Signature Elite system for point-of-care Hemostasis testing, and VerifyNow™ platelet reactivity testing system.
- **HemosIL HIT Ab and HemosIL Liquid D-Dimer HS 500 controls**, developed by Biokit, were marketed in the USA.



Acute Care Diagnostics

Integrative solutions at the speed of life

Our integrated and comprehensive Acute Care Diagnostics business line, from our company Instrumentation Laboratory, helps clinicians and laboratorians achieve better patient outcomes, lower the cost of care, ensure regulatory compliance, and enhance operational efficiency in hospital Acute Care settings. From Cardiovascular Operating Rooms and Catheterization Labs to Intensive Care Units and Emergency Departments, our Acute Care Diagnostics solutions address today's healthcare challenges by improving efficiency and enhancing patient care.

Our comprehensive and integrated line includes the GEM® Premier™ Family of blood gas testing systems, Avoximeter™ point-of-care CO-Oximeters, and the Whole Blood Hemostasis Family, featuring the ROTEM, Hemochron and VerifyNow product lines.

GEM Premier Family systems simplify operations at the point-of-care by automating key labor and skill-intensive tasks with Intelligent Quality Management (iQM®/iQM2) and maintenance-free, all-in-one PAK cartridges. Data management system, GEMweb® Plus 500 Custom Connectivity, combines control of information, analyzers, and operators into one intuitive information management system.

Our Whole Blood Hemostasis product line is designed to help clinicians make key transfusion, bleeding risk, and anticoagulant dose adjustment decisions during surgical and interventional procedures.

New Products & Highlights of 2017

- **Accriva Diagnostics**, a global leader in *in vitro* diagnostic blood testing at the point-of-care, including its flagship product portfolio spanning coagulation, platelet aggregation, CO-Oximetry and incision devices, was acquired by Werfen, through its company Instrumentation Laboratory, in January 2017.
- **New data management system, GEMweb Plus 500 Custom Connectivity**, launched worldwide in July 2017, providing complete control of GEM Premier testing systems, including the new GEM Premier 5000 with iQM2. Expanding upon the original GEMweb Plus platform, GEMweb Plus 500 offers enhanced functionality, workflow, and mobility.
- **New GEM Premier 5000 with iQM2 and GEMweb Plus 500 Custom Connectivity** were featured for the first time at the 69th Annual Scientific Meeting of the American Association for Clinical Chemistry, along with newly acquired ROTEM, Hemochron, VerifyNow and Avoximeter systems, in August 2017.



Hemochron
and cuvettes

"The GEM Premier 5000 blood gas testing system forms an essential part of our approach to rapid patient management. With its integrated iQM2 software, our users are guaranteed optimal analytical performance and accurate and precise results. This assurance is paramount when dealing with patients who present with acute symptoms, requiring swift decisions. In intensive care, operating rooms, and respiratory units, the GEM Premier 5000 system has proven to be a successful addition to our point-of-care testing repertoire."

Tony Cambridge, MSc.

Lead Biomedical Scientist. Blood Sciences and POCT. Derriford Hospital, Plymouth, UK



Autoimmunity

Redefining autoimmunity

Throughout its history as an innovator in autoimmune diagnostics, our company, Inova Diagnostics, has been driven by a simple mission: help labs improve the way patients with autoimmune diseases are diagnosed, monitored, and treated. Since 1987, we have been working continuously with clinical researchers to develop new biomarkers for more accurate testing. We also collaborate with experts in automation to deliver more efficient systems, which help clinical labs improve their testing processes.

Diagnosis of autoimmune diseases can be extremely challenging. We help with this difficult task by bringing labs, and the clinicians they serve, new biomarkers for earlier, more accurate diagnosis. We continue to invest in the development of new systems to streamline autoimmune laboratory workflow, and improve turnaround time for more efficient patient care.

Our comprehensive product portfolio includes systems and reagents such as the BIO-FLASH® and QUANTA Flash®, which support the diagnosis, stratification, and monitoring of complex disorders, such as connective tissue disease, rheumatoid arthritis, antiphospholipid syndrome, vasculitis, and celiac disease.



QUANTA-Lyser® 3000

New Products & Highlights of 2017

- In the fourth quarter of 2017, we launched **QUANTA-Lyser® 3000**, a fully-automated EIA (enzyme linked immunoassay) and IFA (immunofluorescence assay) processor. QUANTA-Lyser 3000 represents the next generation of EIA and IFA processors, ensuring assay traceability with an on-board camera that automatically scans 2D reagent barcodes. QUANTA-Lyser 3000 introduces individual well washing and the ability to pipette IFA slide-mounting media to facilitate direct transfer onto NOVA View® digital IFA microscopes, without the need to coverslip slides.
- **QUANTA Flash® Calprotectin** is an assay that aids in the diagnosis of Inflammatory Bowel Disease (IBD) and can help differentiate IBD from Irritable Bowel Syndrome (IBS). In the first quarter of 2017, the assay became available in territories where diagnostic products with the CE mark may be marketed. Our company Biokit provides one of the raw material components of the QUANTA Flash Calprotectin assay.
- We launched the first ANCA IFA assays to be cleared by the US Food and Drug Administration (FDA). **NOVA Lite® DAPI ANCA (Ethanol)** and **NOVA Lite® DAPI ANCA (Formalin)** kits are for use with NOVA View and represent a long-awaited solution for laboratories performing ANCA IFA testing.

"Fecal calprotectin has revolutionized my clinical practice. Calprotectin measurements taken during the diagnostic workup, when the diagnosis could be either IBS or IBD, provide direction and important information prior to endoscopic evaluations. Calprotectin testing supports a patient-centered, proactive approach to disease management, allowing accurate detection of indolent and often-missed inflammation. The highly accurate QUANTA Flash Calprotectin assay offered by Inova Diagnostics, with a broad quantitative range, is an asset to the clinician's decision-making process."

KT Park, MD, MS, Chair of Clinical Care and Quality, NASPGHAN and Co-Director, Stanford Children's IBD Center at Stanford University School of Medicine, CA, USA

Staying close to the people we serve

To keep close to the people we serve, Inova Diagnostics periodically invites practitioners and patients to share their stories. We recently hosted a local high school student, Michael, and asked him to share his story. To a packed room of employees, Michael told the story of how it took several years for his doctors to determine that his slow growth and "failure to thrive" may be related to celiac disease. Although asymptomatic, his physician was able to diagnose Michael's celiac disease using our diagnostic test kit. Michael shared his experience, explaining that he has grown more than 12 inches since his diagnosis and how understanding his condition has allowed him to control the disease, rather than the disease controlling him. After meeting with company staff, one of the highlights of Michael's visit was seeing the labs and facilities where these diagnostic tests are developed and manufactured.



Michael sharing his story



In Vitro Diagnostics

Other areas of expertise in IVD

To reinforce our leading role in the field of IVD, our business also includes the following areas of expertise:

- Original Equipment Manufacturing (OEM)
- Clinical Software
- Clinical Chemistry
- Infectious Disease Serology

→ Original Equipment Manufacturing (OEM)

Our OEM solutions, from our company Biokit, consist of Proprietary Products and Custom Development & Manufacturing Services. Over 80 long-term customers in the IVD industry source immunoassays and biomaterials from us—in fact, six of the top ten IVD manufacturers are our clients—and we are consistently rated as a top-quality supplier.

New Products & Highlights 2017

- Commercial launch of two **OEM CLIA** assays for one of the top five IVD manufacturers.
- Obtained **CE Mark for six assays** on the new platform of one of the top five IVD manufacturers.
- Completed the move to the **new, state-of-the-art Can Montcau site** near Barcelona (Spain).
- Recognized as the “**Innovation Partner of the Year**” by one of the top five IVD manufacturers.
- Signed License and Material Transfer agreement for **Nanopeptamer Technology**.
- **Development, validation, and manufacture of a critical antigen** used by a third party in a high volume assay.



Our solutions enhance patient care and facilitate the management of information in hospitals and laboratories around the world.

→ Clinical Software

We are committed to developing secure, 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.

New Products & Highlights 2017

- In November, our Clinical Software team obtained the **Medical Device (MD) Manufacturer License** granted by the **AEMPS (Spanish Agency of Medicines and Medical Devices)**. From now on, we will be a manufacturer of MD software for anticoagulant therapy (AT) support. The MD Software is currently being distributed by Werfen in Iberia and Italy.
- **Werfen IT & Software Skills Program** was launched in order to reach a maximum level of excellence in our software support teams in North America, Latin America, EMEA¹, China, and the APAC² region.



¹ Europe, Middle East, Africa and India

² Asia-Pacific

In Vitro Diagnostics

→ Clinical Chemistry

We offer easy-to-use clinical laboratory instrumentation and reagents for chemistry and pharma-toxicology labs. Our unique solutions, from our company Instrumentation Laboratory, are used to diagnose conditions such as diabetes and to detect drug abuse.

New Products & Highlights 2017



→ **quantILab®** rebranding of Clinical Chemistry reagents was completed at both Ascoli (Italy) and the facilities of our company Biokit near Barcelona (Spain).

→ **quantILab® Calcium Arsenazo**, a new liquid assay for calcium determination with excellent on-board stability, which is useful in the diagnosis and monitoring of bone, kidney, parathyroid gland, and gastrointestinal diseases, was marketed in the EU and other territories.

→ **quantILab® Microalbumin(II)**, a new liquid assay with excellent linearity in the lower range, which is useful for evaluating diabetic patients to assess the potential for early onset of nephropathy, was marketed in the EU and other territories. The assay was developed by our company Biokit.

→ **quantILab® Glycated Albumin**, an innovative assay for diabetes management, was successfully launched in Italy, generating strong interest among the scientific community. Independent multi-centric evaluations of the assay resulted in papers published in *CCA*, *International Journal of Clinical Chemistry and Diagnostic Laboratory Medicine*, and *CCLM, Journal of Clinical Chemistry and Laboratory Medicine*.



→ Infectious Disease Serology

Nearly 50,000 men, women, and children die each day from infectious diseases.¹ Our experience in a variety of IVD technologies allows us to offer a wide range of immunoassay tools, from our company Biokit, used for the detection of infectious diseases such as syphilis, hepatitis (A, B, C), ToRCH (infections of a developing fetus or a newborn), Chagas (tropical parasitic disease) and retroviruses (HIV and HTLV).

New Products & Highlights 2017

→ Successful validation of **HSV-2 (Herpes simplex virus type 2) rapid test** by one of the USA's major commercial labs.



¹ Source: World Health Organization, 2017

Medical Devices

Our Medical Devices business division reinforces our position as a leading global healthcare technology corporation worldwide. The division encompasses the following areas of expertise.

- Infusion Therapy
- Medical Devices & Scientific Instrumentation Distribution

Medical Devices accounted for 14% of total revenue for Werfen in 2017, with sales generating 192 million euros. The business continued its positive trend with an increase of 2.4% against the previous year.

→ Infusion Therapy

Our single-use, continuous infusion systems from our company Leventon are used in the treatment of ambulatory patients to promote patient recovery and improve quality of life by increasing patient mobility.

New Products & Highlights 2017

Dosi-Fuser is becoming the standard pump for home care:

- **Exclusive use** of Dosi-Fuser in the best known cancer centers in the USA and around the world.
- Scientific posters demonstrate that Dosi-Fuser **increases patient satisfaction and saves costs** compared to electronic pumps.
- **Market leader** for the first time in France, maintained position as market leader in Portugal, and growth in many other markets.

Quality improvements to our Dosi-Fuser pumps to meet customer expectations:

- **Reorganization of the manufacturing process** to increase expertise and know-how.
- Progress with the **implementation of automated procedures** to obtain a more robust product.

- Improvement of the main element that makes our product unique: **The Capillary Device**.
- **ISO certified suppliers** as standard to ensure the quality of our end product.

 **Leventon**
A Werfen Company

→ Medical Devices & Scientific Instrumentation Distribution

We act as distributors of both our own and third-party medical devices, such as disposables, orthopedic implants, and surgical instruments, and also third-party scientific instrumentation.

New Products & Highlights 2017

- **Distribution agreement** for Spain signed between Izasa Hospital and Serres, a company focused on suction systems for a variety of surgical needs.
- Izasa Scientific began **distribution of Fluidigm**, single cell preparation and digital PCR systems for genomic applications, in the Iberian Peninsula.
- Medicinália-Cormédica entered the **field of Negative Pressure Wound Therapies** with KCI products.
- Nicolai successfully launched a surgical hemostatic agent, **PuraStat**, in Germany, selling it to more than 100 hospitals during its first year in the market.
- Comesa Hungary signed a **new long-term agreement** with Zimmer-Biomet, a leading medical device manufacturer specializing in orthopedic products.

 **Comesa Austria**
A Werfen Company

 **Comesa Hungary**
A Werfen Company

 **Comesa Poland**
A Werfen Company

 **Izasa Hospital**
A Werfen Company

 **Medicinália Cormédica**
A Werfen Company

 **Nicolai**
A Werfen Company

 **Izasa Scientific**
A Werfen Company

Talent

As the healthcare industry grows and evolves, so do we. At Werfen, we are transforming the way we think about our role in the industry, and how we develop our people and talent. Our success as a company depends on having the right talent, in the right place, and at the right time, both now and in the future, which is why one of our top priorities is to create value through our people.

In this respect, 2017 was a very interesting year, which saw a number of initiatives launched. Many key projects were aimed at People Managers.

“Werfen Voices” Engagement Survey



In 2017, Werfen launched its first-ever worldwide engagement survey. We understand engagement as the extent to which employees are motivated to contribute to the success of our organization. With a participation rate of 93.4%, this survey has enabled us to listen to our employees and understand how they feel about working for Werfen. It has also allowed us to conduct a benchmarking exercise for

the entire employee population and against general norms.

It was very encouraging to see that the great majority of our employees say that they are proud to work at Werfen!

The next step is for managers to develop action plans to make improvements in the highlighted areas.



We are holding our managers accountable and have set the bar higher than ever.

Global network to provide insights and perspective on all HR initiatives.

Feedback tool to help people managers develop management capabilities.

The Role of the Manager

We hold our managers accountable, and have set the bar higher than ever.

Werfen recognizes that when our people managers (those with one or more direct reports) are competent, accountable, and engaged, they achieve better results, which impacts productivity, morale, and engagement in their teams. This is why we are investing considerably in this critical target audience, and why we made 2017 “The Year of the Manager” at Werfen.



Werfen People Manager Ambassador Network

This global network was created last year with representatives from all sites and most affiliates across Werfen. This key governance forum provides solid insight into, and perspective on, all HR initiatives throughout the full life cycle of each project.



Assessment and Feedback Tool

In 2017 we launched an assessment and feedback tool to help people managers develop management capabilities. We encouraged our managers to solicit, and listen to, feedback from their direct reports and line managers in order to better understand their strengths and identify areas for development.



Talent

Why Werfen?

Werfen is a growing, privately held company with strong values that go hand-in-hand with excellent performance and results. Our people, a diverse group of talented individuals from all corners of the world, are our most valued asset and the key to the success of our company. At Werfen, every person counts and can make a difference and, with us, commitment, passion, and great results are always recognized and rewarded.

This is what our people say...

Company Strength

- Global leader in Hemostasis, Acute Care Diagnostics and Autoimmunity
- Growing, privately held company with a long-term vision
- Technology pioneer with an unwavering focus on R&D
- A diverse group of talented individuals from around the world



"What attracted me to Werfen was its unwavering focus on R&D and innovation, and their long-term commitment to redefining IVD testing worldwide."

Juan Peng
Autoimmunity Business Unit Director,
Werfen in China

The Werfen Culture

- Promoting integrity and teamwork
- Encouraging empowerment and delegation
- Dedication to continuous improvement and customer-driven innovation
- Focus on making a positive impact in the world



"Working daily to improve patient care helps us grow as an organization, as professionals, and as human beings."

Jordi Rubiralta
President of Werfen

At Werfen, every person counts and can make a difference and, with us, commitment, passion, and great results are always recognized and rewarded.

Career Growth

- Professional and personal development for all employees
- Multiple career paths
- International career opportunities at our sites and affiliates worldwide



"During my 15 years with Werfen, I have been empowered to make decisions and solve problems with the support and trust of our management. I am proud to work for a company where every person counts and can make a difference."

Linda Orlandi
Molecular Diagnostics
Business Unit Manager,
Werfen in Italy

Rewards and Recognition

- Recognizing and rewarding our employees' value and talent in a customized way
- Service awards
- Market competitive compensation



"Over the past 6 years, we have been able to manage significant growth in production volumes while improving costs and maintaining quality. I am very pleased that these efforts have been supported and recognized by Werfen."

Mark Olsen
VP of Operations,
Instrumentation Laboratory



Annual Report 2017





ABOUT US

Corporate Governance

Our Values

Corporate Citizenship

Quality Policy

Milestones

Corporate Governance

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



Board of Directors

The primary decision-making body, responsible for the administration and representation of Werfen. Its main responsibilities include:

- Establishing the overall strategy and economic and financial objectives for Werfen.
- Defining corporate plans and policies.
- Overseeing the development of the business.
- Ensuring the future viability and competitiveness of Werfen.
- Ensuring adherence to the highest standards of ethical business conduct.

Jordi Rubiralta, *President*

1

José Luis Rubiralta, *Director*

2

Xavier Rubiralta, *Director*

3

Marc Rubiralta, *Director*

4

Carlos Pascual, *CEO*

5

José Luis Guerrero, *CFO*

6

Germán Castejón, *Independent Director*

7

Miquel Roca, *Non-Director Secretary*

8

Complying with legislation, regulations, and Werfen policies is the first and most important job of all Werfen employees.

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.

Jordi Rubiralta, *Chairman*

Marc Rubiralta, *Member*

Carlos Pascual, *Member*

José Luis Guerrero, *Member*

Audit and Control Committee

This committee reports directly to the Werfen Board of Directors in order 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*

Marc Rubiralta, *Member*

Germán Castejón, *Member*

Miquel Roca, *Member*

Compliance Officer

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

Albert Garicano, *Compliance Officer*



Code of Ethics

The Werfen Code of Ethics establishes our commitment to ethical business practices and sustainable development, and clearly expresses the expectations of Werfen as an employer by providing practical guidance and references. Complying with laws, regulations, and Werfen policies is the first and most important job of all Werfen employees.

Werfen firmly believes that integrity is—and will remain—one of the core pillars upon which our reputation is based, and the foundation of a sustainable and successful business. Employees are encouraged to speak up if they ever have a compliance concern. We have established an Ethics Channel through which employees can inquire about the application of the Code or report any conduct that they believe could contravene the ethics, legislation, or standards governing Werfen.

In 2017, we also emphasized the importance of Compliance and conducting business in an ethical and sustainable way by organizing a number of initiatives, including training sessions, for all employees across the organization.

Our Values

Werfen has a set of company values to help employees achieve their own goals and those of the company. They are the essence of the company's identity.





Integrity

Honesty & Humility, Respect for People

We always live up to our word. We say what we mean, and we mean what we say. We are direct and straightforward, and we deliver in line with the expectations we have created, allowing us to build trust and credibility among our customers and stakeholders.

Leadership and Management

Teamwork, Innovation

We are committed to a culture of strong leadership and collaborative teamwork, which allows us to implement our company's strategy and mission in a purposeful way. We continue to invest in innovation because it is the catalyst for the growth and success of our business, and the key to our competitive advantage.

Delivery of Results

Quality & Excellence, Customer Focus

We are fully committed to accomplishing our mission and strategic long-term goals. We are dedicated to exceeding the expectations of our customers and stakeholders, and to going the extra mile that sets us apart from others.

Corporate Citizenship

Giving back to society is an integral part of the way we do business—our ultimate goal as a company is to improve healthcare and human well-being around the world. We work continuously to deliver the best solutions and services to help achieve that goal.

Community Affairs

→ Supporting the employment of the intellectually disabled

For over 28 years, Fundació Portolà has focused on meeting the social and employment integration needs of the intellectually disabled. Werfen is proud to work with this foundation, which enables these individuals to work for a fair salary and to have access to vocational training, soft skills improvement and opportunities for social integration.

Through our collaboration with Fundació Portolà, opportunities have been created for individuals to:

- Work at our headquarters, the Werfen Tower in Barcelona, performing gardening and maintenance tasks
- Landscape and maintain the new facilities of our companies Biokit and Leventon
- Make holiday decorations, bookmarks, greeting cards, and gifts at our company offices
- Make more than 300,000 mesh bags annually for Leventon dossiers



Fundació Portolà

We are committed to supporting and giving back to our local communities.

→ **Raising awareness about careers in Life Sciences and Manufacturing**

As part of National Manufacturing Day, Inova Diagnostics hosted a visit from local STEM (Science, Technology, Engineering, and Mathematics) students to raise awareness of careers in Life Sciences and Manufacturing. In attendance were 30 students, along with their teachers and a host from Junior Achievement San Diego, a not-for-profit organization that aims to teach young people about how to get a job, start a business, manage money, and to foster an understanding of how the real world works. The students toured the facility, and had the opportunity to meet a panel of four Inova team members, who described their paths from school to their current careers at the company. The students were very appreciative of the opportunity to gain a better understanding of the “many paths to success” and the wide range of opportunities within Life Sciences. For the Inova team, it was a rewarding opportunity to support our industry and give back to the community.

→ **Promoting physical, psychological, and emotional health**

Seeking to contribute to the community in which we operate, Werfen in Colombia entered into an agreement with Fundación Doctora Clown (Doctor Clown Foundation) for 2017-18 that includes volunteer activities and workshop groups. Since 1998, the foundation has been working with hospitals, shelters, and organizations supporting at-risk communities, in various social environments, to promote physical, psychological, and emotional health through the use of laughter therapy.

Corporate Citizenship

Charitable Giving & Volunteering

→ Helping to improve the lives of cancer patients

Two teams from Biokit participated in the 5th annual Oncotrail, a 100 km charity race raising funds to improve the lives of cancer patients. The event, organized by Fundació Oncolliga Girona, was particularly emotional because the teams were paying tribute to a colleague, Betty Martinez, who recently passed away following a battle with cancer.



Oncotrail

→ Matching employee donations and supporting the local community

The Matching Gift Program at Instrumentation Laboratory (IL) matches up to \$200 for every employee who donates to an eligible, not-for-profit organization, each year. In 2017, IL gifted to many charities, including the Open Pantry of Greater Lowell to relieve hunger in the local community.

Inova Diagnostics also hosts a Giving Window every year to support local charities. In 2017, Priscilla Carrion, a Supervisor at Inova, championed a “jacket drive” to collect jackets for children and teenagers at the Centro de Atención Múltiple school for mentally and physically disabled children. Through Priscilla’s efforts, and the generosity of the Inova team, over 100 families benefited from this initiative. This brings the total number of families who have benefited from the support of Inova employees over the years to more than 1,200.



Inova Diagnostics Giving Window

Jackets were handed out at a Minion-themed party (based on the animated movie *Despicable Me* (2010) directed by Pierre Coffin and Chris Renaud), where Priscilla dressed up as a Minion to hand out jackets to the children.

We are committed to reducing the environmental impact of our activities.

Sustainability Practices



→ Commitment to protecting the environment

At Werfen, we are committed to protecting the environment. Our manufacturing facilities at Orangeburg, New York (USA) and Bedford, Massachusetts (USA), and our logistics centers in Roncello, Lombardy, (Italy), Tarancón, Cuenca, (Spain), and Le Pré-Saint-Gervais, Paris, (France) are all ISO 14000 certified. This demonstrates that we manage our environmental responsibilities in a systematic manner and in compliance with international and local environmental regulations.



Werfen Sustainability Week

→ Encouraging sustainability

Werfen organized a variety of educational activities, at Werfen Tower headquarters, around the importance of reducing the ecological footprint of our workplace. During our Sustainability Week, employees were given a personalized reusable water bottle, with the aim of ending the use of plastic cups and non-reusable water bottles. We also focused on reducing our power consumption by minimizing the use of elevators, which are major consumers of energy at Werfen Tower. Saving paper and, therefore, trees, was also a major focus. When turning on their computers every day, our employees were greeted by an animated infographic. This was designed to make people think twice before printing!

Quality Policy

Quality is one of the most important drivers behind our success. We strive to meet the highest quality standards across all business lines and geographical areas in order to comply with the most stringent regulatory and compliance requirements worldwide.



ISO 9001 and 13485 Quality Systems

These certifications ensure that the organization provides medical devices and related services that consistently meet customer and regulatory requirements, and that the organization continuously aims to improve customer satisfaction. ISO 9001 is the world's most extensively used ISO certification and ISO 13485 is the most popular certification among medical devices companies. Both systems cover all product/service related processes such as purchasing, manufacturing, customer orders, HR, warehousing, technical service, training, and post-market activities.

• International Registrations

Werfen products are registered with the competent authorities in a large number of countries worldwide, for marketing in those countries. This means that our manufacturing sites comply with country-specific regulations such as: FDA (US), CE (Europe), ANVISA (Brazil), CFDA (China), MFDS (South Korea), PAL (Japan), TGA (Australia), etc.

• International Healthcare Manufacturers Organizations

Werfen is an active member of various international associations for Medical Device/IVD manufacturers, such as MedTech (Europe), Advamed (US), FENIN (Spain), etc.

All our manufacturing facilities, logistics centers, and distribution companies around the world are certified with one of these standards. Also, Corporate Services at Werfen are currently implementing a Quality System based on the latest version of ISO 9001.

ISO 14001 Environmental Systems

This certification ensures 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.

ISO 27001 Data Safety Systems

This external certification demonstrates that the organization safeguards the security of assets such as financial information, intellectual property, employee data, and information entrusted to the company by third parties. This standard has been certified in our UK affiliate.

We are improving the quality of life of patients through innovation.

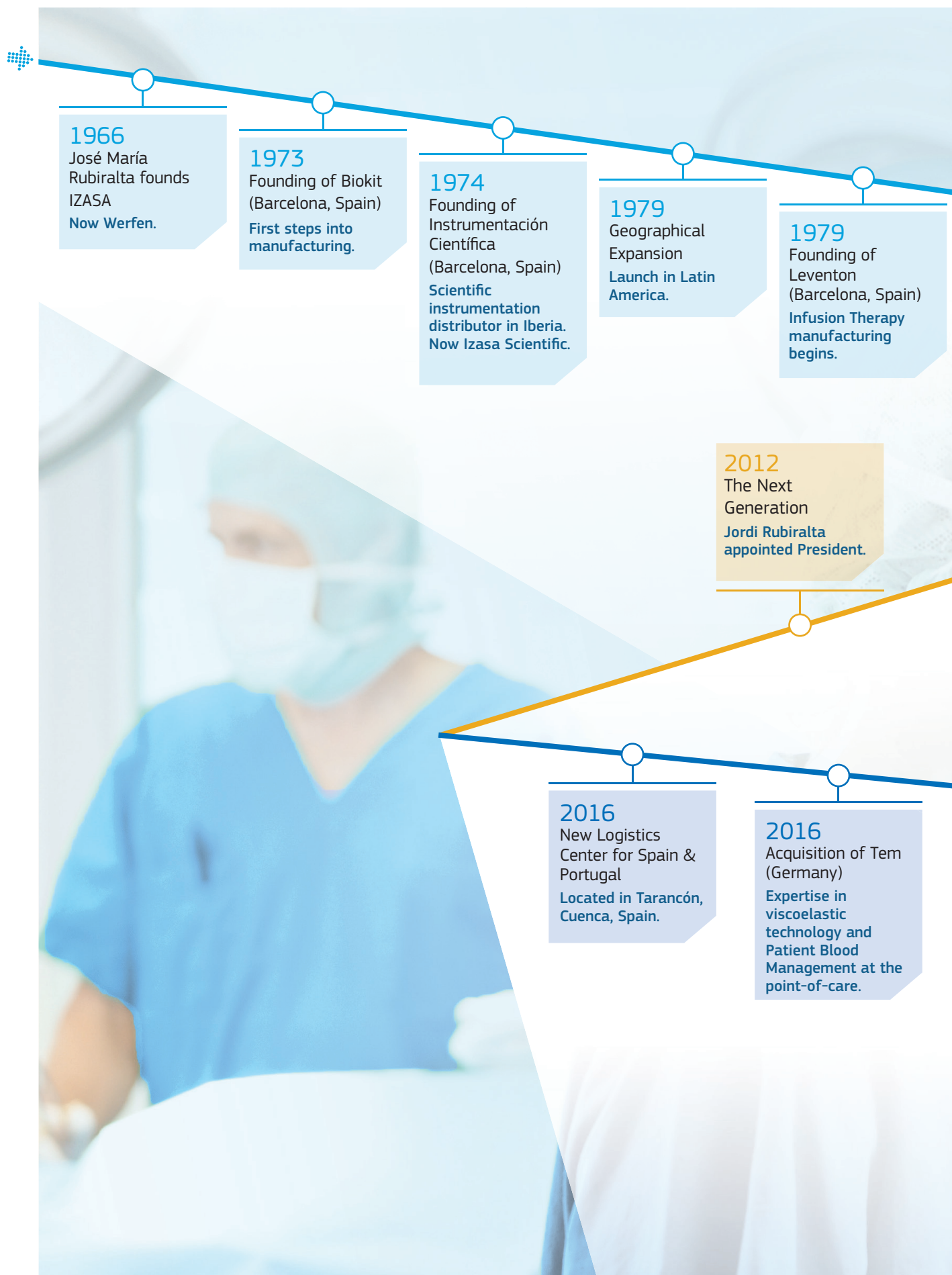
We ensure that the needs of our clients are always met, and legal and regulatory requirements are fulfilled.

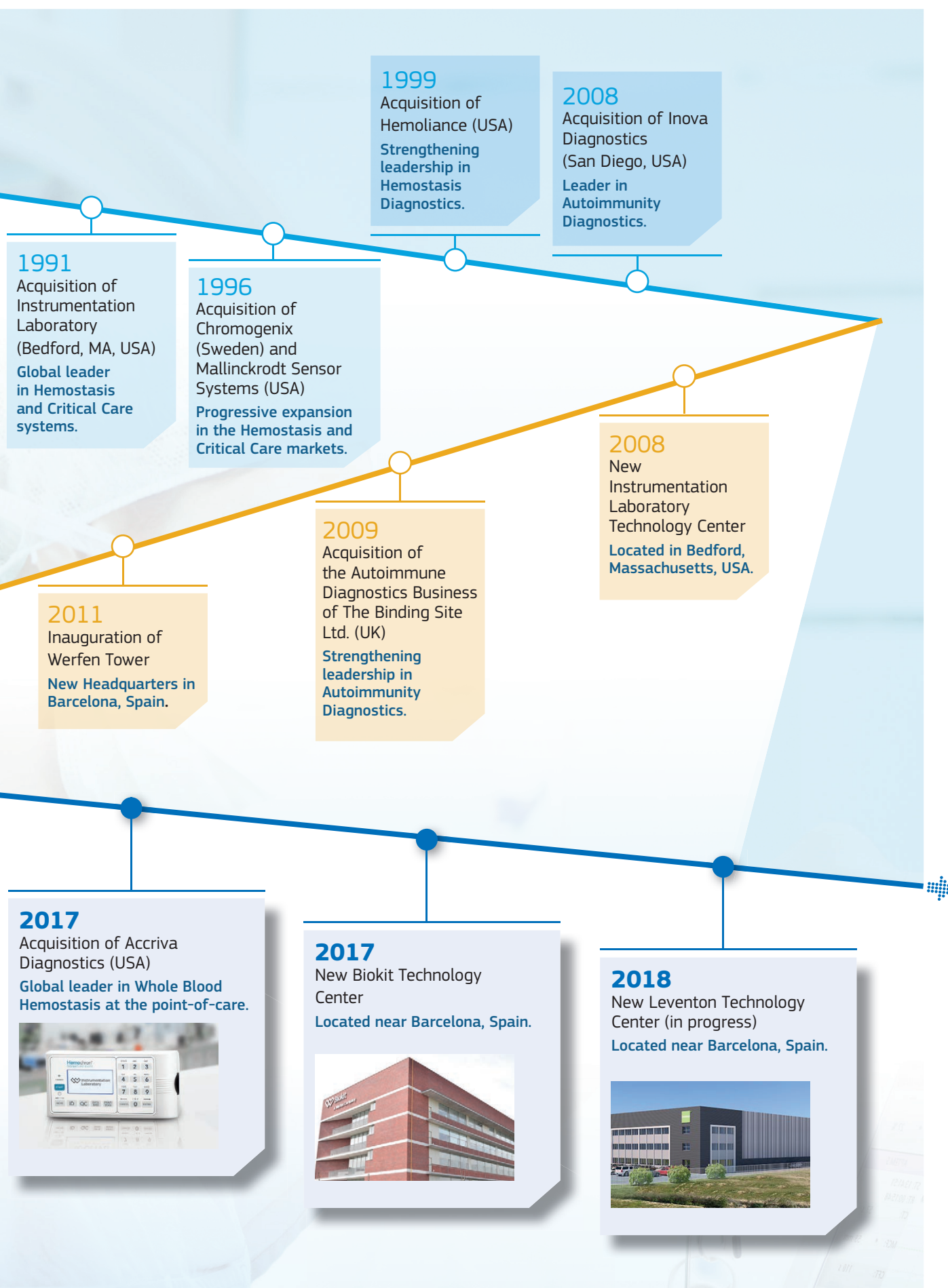
Werfen Quality Policy

The Werfen Quality Policy is derived from our company values and consists of the following principles:

- Marketing products of the highest quality, which employ the latest technology.
- Ensuring that the needs of our clients are always met, and legal and regulatory requirements are fulfilled.
- Always keeping abreast of advances in technology in order to offer state-of-the-art solutions to our customers.
- Offering efficient and customized post-sales services such as ongoing user training, specialized technical services, and a helpline for inquiries and equipment repairs.
- Promoting a positive work environment at Werfen.
- Improving the quality of life of patients through innovation.
- Encouraging the organization to live by these quality objectives.

Milestones







Annual Report 2017



APPENDIX

Glossary

Corporate Highlights

Glossary

Acute Care

The specialized management of life-threatening conditions requiring rapid, comprehensive patient care and frequent monitoring—usually in intensive care units, emergency rooms, and operating theaters.

Albumin test

Blood test measuring albumin, to screen for and help diagnose a liver disorder or kidney disease and to evaluate nutritional status, especially in hospitalized patients.

Anti-neutrophil cytoplasmic antibody (ANCA)

Group of autoantibodies against antigens in the cytoplasm of neutrophil granulocytes (the most common type of white blood cell).

Autoimmunity

Occurs when the body's immune system fails to recognize itself, resulting in antibodies being directed against the body's own tissues (autoantibodies). Autoimmune diseases are caused by autoantibodies and include rheumatoid arthritis, systemic lupus erythematosus, celiac disease, and many other diseases.

Calprotectin

Protein found in stools. Elevated calprotectin indicates intestinal inflammation, usually as a result of inflammatory bowel disease.

Chemiluminiscent (CLIA) assay

Based on Antigen (Ag) -Antibody (Ab) reaction, where the reaction is detected using chemiluminescence (the production of light from a chemical reaction, generally within the visible spectra).

Clinical Chemistry

Uses chemical processes to measure levels of chemical components in body fluids, such as blood and urine, for diagnostic and therapeutic purposes.

Clinical Software

Software solutions that facilitate information management in hospitals, laboratories, and other healthcare facilities, to improve the quality of patient care.

D-dimer (DD) assay

Diagnostic assay to determine the concentration of D-Dimer in human citrated plasma. Used to help rule out clotting episodes (thrombosis) and to help diagnose conditions related to thrombosis.

Enzyme-linked immunoassay (EIA)

Laboratory technique using colorimetric dyes to detect the presence of antibodies bound to specific antigens on a solid surface.

Hemostasis

The balance of the interaction between blood coagulation proteins, platelets and the vessel walls, which maintains blood flow. Disorders or disturbances of any of these factors may result in bleeding or thrombosis, which can be associated with major adverse clinical events.

Hemostatic Agents

Products used as an adjunct or alternative to standard suturing techniques to control bleeding.

Heparin-induced Thrombocytopenia (HIT) assay

Diagnostic assay to determine total immunoglobulin in human citrated plasma that reacts with Platelet factor 4 (PF4) when complexed to heparin. Heparin associated antibodies are commonly found in patients with heparin-induced thrombocytopenia or thrombosis (HIT).

HSV-2

A virus that is almost exclusively sexually transmitted, causing infection in the genital or anal area (genital herpes).

Indirect fluorescent antibody (IFA) test

Indirect fluorescent antibody (IFA) testing is a laboratory technique that uses fluorescent dyes to detect the presence of antibodies that are bound to specific antigens.

Infectious Disease Serology

Laboratory technique using fluorescent dyes to detect the presence of antibodies bound to specific antigens.

Inflammatory Bowel Disease (IBD)

An autoimmune disease of the digestive system.

Infusion Therapy

Delivering medication into a vein through a needle or a catheter.

Irritable Bowel Syndrome (IBS)

Functional disorder of the digestive system, less serious than IBD.

Nanopeptamer Technology

Therapeutic technique using a vacuum dressing to promote healing in acute or chronic wounds.

Negative Pressure Wound Therapy

Therapeutic technique using a vacuum dressing to promote healing in acute or chronic wounds.

Microalbumin test

Test to detect albumin levels in urine, used to detect early signs of kidney disease in those with diabetes or other risk factors, such as high blood pressure.

Original Equipment Manufacturing (OEM)

Offering products and services to other companies.

Rapid test

Diagnostic tests for when a preliminary screening test result is required. Quick and easy to perform, requiring little or no additional equipment.

Thrombosis

Formation of a blood clot inside a blood vessel.

Corporate Highlights

January

- Acquisition of Accriva Diagnostics

February

- Building work began for the new Leventon Technology Center, located near Barcelona (Spain)

March

- Began the move to the new Biokit Technology Center, located near Barcelona (Spain)

June

- Werfen became the corporate brand for all our businesses

August

- Official opening of Werfen in Colombia

September

- Werfen impressed at the 69th American Association for Clinical Chemistry (AACC) Expo

October

- Launch of the Werfen Voices Employee Engagement Survey
- Opening of the new Logistics Centers in Uruguay and Brazil

November

- Launch of new websites for Werfen and Instrumentation Laboratory
- Compliance training for all employees
- The end of our 50th anniversary year

2017



