



Annual Report 2018





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



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OVERVIEW

President's Letter



Marc Rubiralta

"We will continue to achieve this by putting patients at the center of what we do, investing in innovation."

Dear all,

It is with great enthusiasm that I write this message to all of you as President of Werfen. It is a special honor for me to hold this position and follow the steps of my father, and then my brother.

José María Rubiralta founded Werfen in 1966 with the dream of improving patient health and quality-of-life around the world. My father was a pioneer in his field—starting from scratch, he imported first-level health technology to Spain as a distributor, and then soon realized that to achieve what he envisioned, Werfen must invest in its own products. He identified a business opportunity and put all his energy into developing his vision; convinced that production and R&D in *in vitro* diagnostics (IVD) were key to ensuring his success.

My brother, Jordi Rubiralta, reinforced this vision and continued to grow Werfen through a strategic approach that combined organic growth and acquisitions. He strengthened our position as a global leader through commercial expansion in the United States and China, while fostering significant professionalization within the organization.

My intent and aspiration as the next President of Werfen is that we continue to be the first choice of the most advanced laboratory and point-of-care healthcare providers worldwide, with best in class IVD solutions. I believe that by providing

accurate and reliable information to healthcare providers, we support them in making better medical decisions that, ultimately, have a positive impact on the efficiency of healthcare systems globally and society, at large.

We will continue to achieve this by putting patients at the center of what we do, investing in innovation, and lastly, but most importantly, empowering our talented employees, which I know to be the best in the industry.

Finally, I'd like to express my gratitude to the Board and my family for supporting me in this new challenge. As President, I am determined to continue embodying the unique spirit of Werfen and its Values, safeguarding its legacy and further building upon the great work we have been doing. Thank you all so much for your support and trust.



Marc Rubiralta
President

Letter from the CEO



Carlos Pascual

"It is remarkable how well our company has performed."

Dear all,

As I look back on last year—in fact, the last few years—it is remarkable how well our company has performed. And, I'm not only referring to our strong financial performance, but also about how much we have accomplished to support our customers, as well as their patients, all around the world.

In 2018 our consolidated sales were **1,359 million euros**, representing an increase of **5.3%** versus the prior year in constant currency, with positive results across all regions.

In vitro diagnostics (IVD), our core business, achieved growth of **6.5%**, driven mainly by **Hemostasis, Acute Care Diagnostics** and **Autoimmunity**.

In 2018, we moved forward satisfactorily with the integration of our most recent acquisitions: Accriva Diagnostics (Whole Blood Hemostasis) and Tem (Patient Blood Management), which have truly strengthened our product portfolio. We also continued our significant investment in R&D, developing the

most innovative solutions for our customers, to facilitate better medical decisions.

In the forthcoming years, we are determined to maintain our global leadership as a specialized IVD corporation. We have set ambitious goals for 2019 and we will continue on working tirelessly to achieve them. I feel confident that with the continued commitment of our talented teams, our technology, and our focus on innovation and value, we will achieve excellent results.

I want to finish by thanking all our Werfen employees for their extraordinary commitment and the results they have achieved. They are the key to our success, today and tomorrow.

Sincerely,



Carlos Pascual
CEO

Our Ethos

Mission

To improve the quality of laboratory medicine worldwide.

Vision

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

Values

In 2018, the Werfen Values were officially launched worldwide. The Werfen team proudly celebrated “Value Day,” sharing posters, flyers and banners showcasing the corporate morals that define our business.

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





Integrity

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

Respect for People

We recognize that people are the most important part of our business. We value the contribution, thoughts, ideas, differences and diversity others bring, and show the utmost respect for everyone with whom 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 in our approach to our work and 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 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 patients, 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 with the knowledge of 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 support through constant communication; and we always remember that behind every sample there is a patient.

Our Structure

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

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



The Team

Worldwide Employees ¹	2018	2017
Employees	5,155	4,938

¹ Average

Locations

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



— Main office

What is *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.

IVD products, reagents and systems are used in the collection, preparation, and examination of specimens taken from the human body.

Source: US Food and Drug Administration, 2018

What are 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, 2018

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

Employees / Discipline	2018	2017	Employees / Area	2018	2017
Sales & Administration	53%	54%	Europe	44%	45%
R&D	11%	11%	North America	42%	41%
Operations	36%	35%	Rest of World	14%	15%

Business


Corporate

 **Werfen** → Headquarters in Barcelona (Spain)


IVD

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

- Hemostasis
- Acute Care Diagnostics
- Clinical Chemistry

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

- Autoimmunity


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

- OEM
- Infectious Disease Serology

 **Werfen**
Diagnostic Solutions for Life

- Clinical Software
- Affiliates

Medical Devices

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

- Infusion Therapy

 **Comesa Austria**  **Comesa Hungary**  **Comesa Poland**  **Izasa Hospital**  **Medicină Cormédica**  **Nicolai**  **Izasa Scientific**

- Medical Devices & Scientific Instrumentation Distribution



Annual Report 2018

PERFORMANCE

Financial Results

Werfen World

In Vitro Diagnostics

Medical Devices

Talent

Quality Policy



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Financial Results

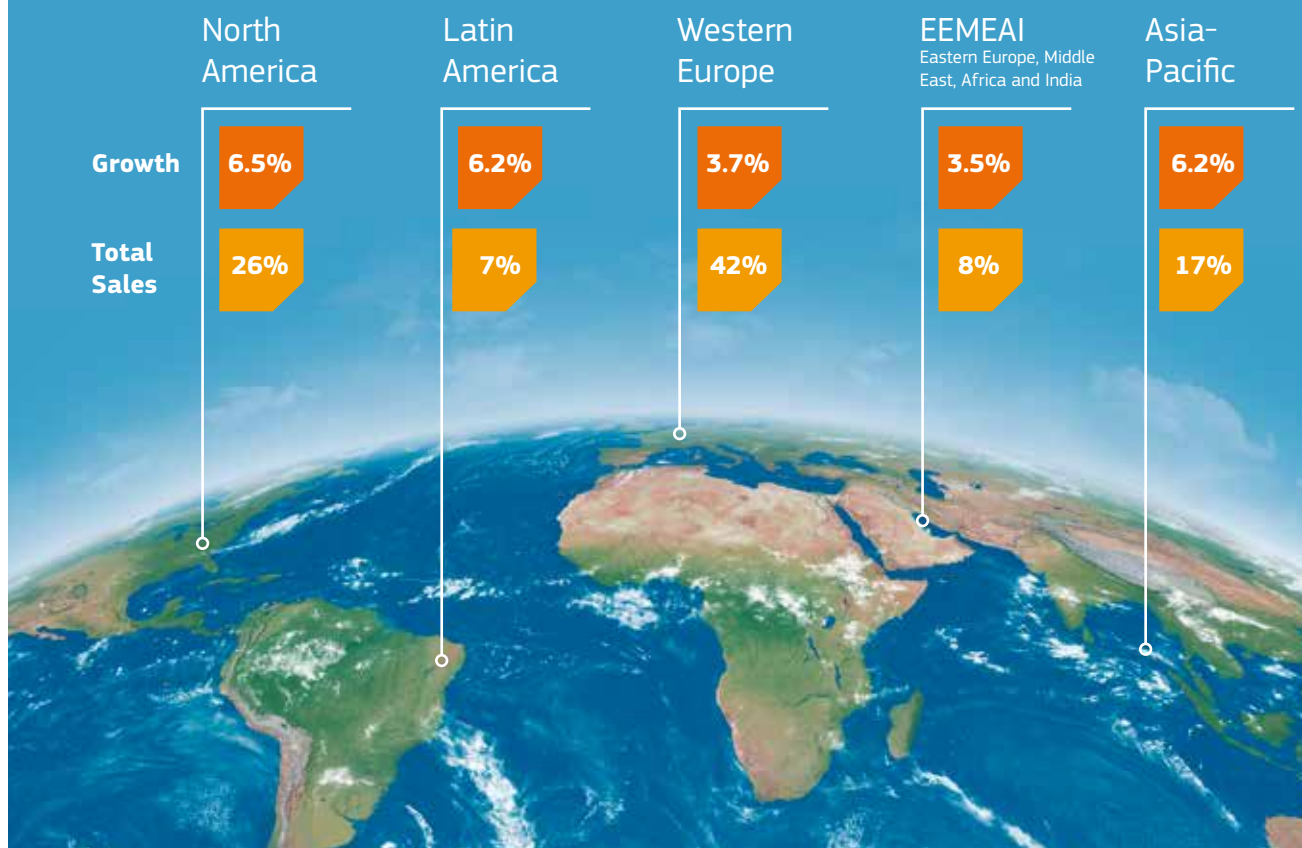
Sales in 2018 reached 1,359 million euros, representing 5.3% growth over 2017 in constant currency terms.

	2018	2017	Growth ¹
	M€	M€	%
IVD	1,183	1,145	6.5
Medical Devices	176	192	-2.2
Total	1,359	1,337	5.3

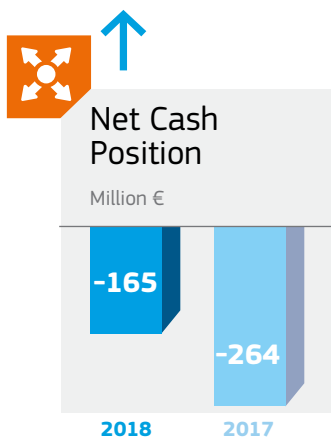
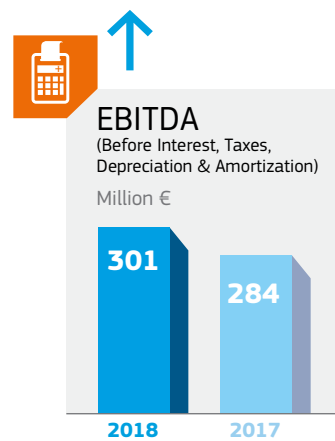
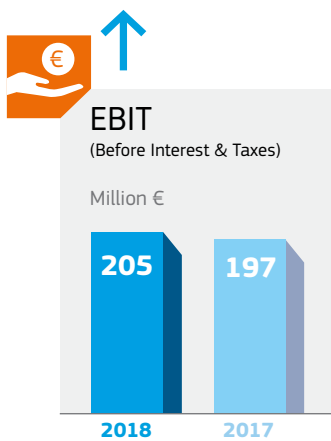
¹ Constant Currency



By Region



Sales in 2018 reached 1,359 million euros.



Australia

In June of 2012, Werfen made the strategic decision to begin direct operations in Australia. Since then, Werfen in Australia has achieved significant success. The Hemostasis business is positioned to be #1 in the near future, GEM® Premier systems are changing the Acute Care Diagnostics market and Autoimmunity has achieved the market leadership position, while reducing overall healthcare costs. Perhaps the most important achievement for Werfen in Australia has been becoming a “destination workplace,” attracting the very best talent on the continent.



→ Highlights of 2018

2018 was a year of consolidation for Werfen in Australia. The growth was led by the Autoimmunity business, which grew 24% over 2017, driven by BIO-FLASH®, coupled with a record number of GEM® Premier Systems placements for Acute Care Diagnostics. For Hemostasis, 72 ACL TOP® Family 50 Series Testing Systems will be placed across the network at New South Wales (NSW) Health Pathology, moving Werfen to #1 in the Australian Hemostasis market.

→ Outlook for 2019

This year is set to be an unprecedented year of instrument placements and growth across all businesses. Specifically, the Acute Care Diagnostics portfolio is expected to achieve record GEM Premier Systems placements, led by the GEM Premier 5000 systems. In Hemostasis, the team will be installing ACL TOP Family 50 Series systems at New South Wales Health Pathology, ensuring that 2019 will be the busiest year in the history of Werfen in Australia.



Australia

North America



Awards Night at the Instrumentation Laboratory Annual Sales & Service Meeting

North America

→ Highlights of 2018

North America is home to our two largest companies, Instrumentation Laboratory (IL) and Inova Diagnostics (Inova), together hosting nearly half (42%) of Werfen employees worldwide (including R&D and manufacturing). In addition to securing more than 7% growth in one of our largest markets, both companies continued to break new ground within the IVD industry. North America represents 26% of our total business.

For IL, North America was a key driver of global growth for Hemostasis and Acute Care Diagnostics, with total sales growing a phenomenal 8% vs 1–3% for the market. Success factors included: outstanding execution of our ValueSelling and Health Economics strategies, excellent integration of Tem (acquired in 2016) and Accriva (acquired in 2017), as well as exceptional talent recruitment, team collaboration, quality products and services. It was a year of major milestones, including securing key US Patents to advance innovations in Hemostasis, Blood Gas and CO-Oximetry testing, in addition to the installation of more than 1,000 GEM® Premier 5000 blood gas systems in medical facilities worldwide.

Inova achieved 8% revenue growth in North America vs 2017, as well as a record number of system placements. A major US reference laboratory standardized the processing of autoimmune ELISA testing, installing newly launched QUANTA-Lyser® 3000 systems throughout its laboratory network. In Research & Development, the team continued progress in the development of Aptiva™*, a novel multi-analyte platform. This highly complex project involves the development of the instrument, as well as a 60+ analyte reagent menu with several new biomarkers.

→ Outlook for 2019

For IL, 2019 is expected to be an exciting year, with robust development of new instrument systems and reagents, many in the final stages of field testing. The company will also celebrate its 60th anniversary of passion and innovation in the IVD industry.

For Inova, 2019 will be another milestone year with the further advancement of Aptiva*, the most significant product development endeavor for the company since its inception. This multi-disciplinary project holds the potential to transform autoimmune disease testing, by helping close the seronegative gap in diagnosis, and dramatically improving the efficiency of testing in the laboratory.



Inova Diagnostics Employees, San Diego, California, USA

*Not available for sale. In development.

Werfen World



Werfen in Italy

Iberia

Spain & Portugal

→ Highlights of 2018

The Werfen in Iberia team recorded a fantastic 2018, with sales growing by an impressive 5.8%, surpassing the IVD market rate. In Hemostasis, the team secured an astonishing market share of 66.5%, exceeding 2017 by 3.4 % and further strengthening its market leadership in Iberia. This success was replicated in its Acute Care Diagnostics business unit, as it overtook the Whole Blood Hemostasis (WBH) market and is now poised to become the market leader in point-of-care testing (POCT).

Werfen in Iberia also saw a growth of 10.3% in Autoimmunity with its BIO-FLASH expansion and Clinical Software. Laboratory Information System (LIS), enjoyed a healthy rise of 33% due to the increased adoption of Modulab across Iberia. Furthermore, the team secured outstanding results in the area of Molecular, achieving 10% growth. All combined, these excellent results consolidated the team's #1 position among IVD companies dedicated to specialized areas, and #4 in the IVD market overall.

→ Outlook for 2019

Building upon the success of 2018, the Werfen in Iberia team is determined to reinforce its position as market leader and remain the industry benchmark. They will continue their team's specialization approach, while prioritizing quality of products and service.

Italy

→ Highlights of 2018

Italy outperformed the domestic market by more than 3% and crossed the barrier of 100M€ sales in one year. All business units and departments contributed to these fantastic results!

Hemostasis led the growth, reaching a market share above 65% and installed their first two Hemocell™ Specialized Lab Automation Workcells.

→ Outlook for 2019

Despite political and economic uncertainties, Werfen in Italy is confident that it will continue its successful path and have another record year in 2019. Thanks to the strength of this consolidated organization and the new methodologies of ValueSelling and Strategic Selling, Italy will continue providing premium diagnostics solutions to laboratories, clinicians and patients—maximizing value for Werfen.



Werfen in Iberia



Iberia

Italy

Korea

Russia

Korea

→ Highlights of 2018

2018 was a record year for Werfen in Korea, the first Werfen Affiliate established in Asia. Korea increased sales by almost 16%, with strong growth across all business units: 9% in Hemostasis, (35% market share); 21% in Acute Care Diagnostics and 56% in Autoimmunity. An experienced and steady team, as well as customer collaboration, have been crucial in achieving this performance.

→ Outlook for 2019

The 2019 outlook for Werfen in Korea is positive, with expectations of growth in overall instrument placements. Furthermore, the newly adopted ValueSelling techniques, as well as powerful corporate tools to manage customer relationships, will be instrumental to the continued growth of Werfen in Korea.



Russia

→ Highlights of 2018

Russia and the Commonwealth of Independent States (CIS) region achieved incredible results with 14% growth—significantly above the market rate. This growth was realized across the mature and saturated Russian market, as well as the rapidly developing markets within the CIS countries, with an outstanding performance of more than 20% in Belarus and Kazakhstan. The biggest single tender in the region was won in Ukraine, with Werfen delivering 32 analyzers as part of a modernization project at eight perinatal centers!

→ Outlook for 2019

Despite macroeconomic limitations and government healthcare expenditure shrinking, the team has an ambitious strategy for Hemostasis sales development in the private segment, particularly with the first of our HemoHub™ Intelligent Data Manager installation, planned in the biggest private lab in Russia. Double-digit growth is predicted for our Acute Care Diagnostics product lines, which will be supported by our ValueSelling and Strategic Selling approach, which is actively implemented by Werfen and its distributors.



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* diagnostics (IVD) testing impacts approximately 70% 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, distributing and supporting IVD testing systems, reagents, 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. These services are used by healthcare providers, from laboratorians and pathologists to respiratory specialists, surgeons, anesthesiologists, and more.



¹ Source: MedTech Europe, 2018.

In vitro
diagnostic (IVD)
testing impacts
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70% of all medical
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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.

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. We are passionate about, and committed to, helping them achieve these objectives.

In 2018, IVD sales reached 1,183 million euros. This represents 87% of total revenue for Werfen.

Our Hemostasis business line grew in line with the market. Our Acute Care Diagnostics business line achieved above market growth with Blood Gas products growing +6%, Patient Blood Management +18% and Whole Blood Hemostasis +13%. Our Autoimmunity business line achieved a 20% market share in 2018.

Organic Growth
(constant currency)

Hemostasis

+4.7%

Acute Care Diagnostics

+8.3%

Autoimmunity

+9.2%

In Vitro Diagnostics

"Today, we perform all Hemostasis testing with HemoCell Specialized Lab Automation. If a sample requires further assessment after the first analysis, specialty testing can be performed without additional blood sampling. This is key for both laboratory efficiency and the patient experience."

Vicente Cortina, Hemostasis Laboratory Technical Manager, VHLabs, Vall d'Hebron University Hospital, Barcelona, Spain

Our Hemostasis business line from 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 for laboratories, including the industry-leading ACL TOP Family 50 Series Hemostasis Testing Systems, HemoCell Specialized Lab Automation, ACL AcuStar® system, HemosIL® assays, and HemoHub Intelligent Data Manager.

Coupled with Hemostasis testing systems at the point-of-care, including the Hemochron™ Signature Elite whole blood coagulation system, VerifyNow™ platelet-reactivity system and ROTEM® viscoelastic testing systems, we now offer a complete Hemostasis Diagnostic Management solution.

Dedicated to supporting healthcare professionals, our Hemostasis solutions are designed to meet the needs of clinicians, hospitals, hospital networks and commercial labs.



HemosIL assays



Hemostasis testing systems

2018 New Products and Highlights

- **Launch of ACL TOP Family 50 Series Hemostasis Testing Systems in China:** With this launch, we completed the commercial release of our leading Hemostasis platform in all major markets.
- **Commercial release of key new HemosIL assays:** HemosIL AcuStar HIT IgG in North America; HemosIL AcuStar Domain I, enhancing our APS panel, and HemosIL SynthAFax[®], for the measurement of novel Hemophilia drugs in North America, Europe and other markets.
- **Record year for placements of ACL TOP Lab Automation System models and HemoCell Specialized Lab Automation,** the world's first lab automation workcell designed specifically for Hemostasis testing, driven by our focus and expertise in workflow, lab automation and value analysis.
- **Worldwide launch of ProDx™ Remote Support suite**—for automated remote, continuous monitoring of ACL TOP Hemostasis Testing Systems at hospitals and commercial laboratories, to ensure peak efficiency and performance.



In Vitro Diagnostics

"Implementation of point-of-care hemostatic testing, including ROTEM viscoelastic testing, within the context of a simple, integrated transfusion algorithm, reduces red cell and platelet transfusions, and major bleeding following cardiac surgery—improving management of coagulopathy in cardiac surgery and supporting broader adoption into clinical practice."

Keyvan Karkouti, MD, Deputy Anesthesiologist-in-Chief, Toronto General Hospital, Canada

Our integrated and comprehensive Acute Care Diagnostics business line from 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 features ROTEM viscoelastic testing systems, the Hemochron™ Signature Elite coagulation system and VerifyNow platelet-reactivity system.

GEM Premier Family systems ensure lab-quality results for enhanced patient management decisions at the point of care. Intelligent Quality Management (iQM®/iQM2) and maintenance-free, all-in-one PAK cartridges simplify operations by automating key labor and skill-intensive tasks. 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 for surgical and interventional procedures.



ROTEM *delta* viscoelastic testing system



VerifyNow platelet-reactivity system



GEM Premier 5000 blood gas system

2018 New Products and Highlights

- **Successful commercial integration of the entire Acute Care Diagnostics Product Portfolio**, including Blood Gas, Patient Blood Management and Whole Blood Hemostasis systems, integrating and simplifying point-of-care testing throughout the hospital.
- **Successful launch of the GEM Premier 5000** blood gas system in North America with key wins throughout the continent, expanding the commercial reach of the system around the world.
- **Commercial release of the new VerifyNow** system in key European markets and other select territories, with a focus on cardiovascular and neuro-interventional clinical applications.
- **Introduction of GEMweb Plus Custom Connectivity** with expanded integration of the entire Acute Care Diagnostics portfolio, enhancing data management at the point of care.



In Vitro Diagnostics

Throughout its history as an innovator in autoimmune diagnostics, Inova Diagnostics has been driven by a simple mission: to 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 this difficult task by bringing labs, and the clinicians they serve, new biomarkers for earlier, more accurate diagnosis. Our commitment to innovation allows us to continually improve the ways we help healthcare professionals address a broad range of autoimmune diseases and close the seronegative gap. Our comprehensive product portfolio includes systems and reagents which support the diagnosis, stratification, and follow-up of complex disorders, such as connective tissue disease, rheumatoid arthritis, antiphospholipid syndrome, vasculitis, inflammatory bowel disease and celiac disease.

We continue to invest in the development of new systems to streamline autoimmune laboratory workflow and improve turnaround time for more efficient patient care. The Integrated Lab is comprised of a portfolio of instruments seamlessly connected to the Laboratory Information System (LIS) using QUANTA Link®, a data management system. Integrated Lab instruments include Aptiva™*, a new system for particle based multi-analyte testing (PMAT), BIO-FLASH® rapid-response chemiluminescent analyzer, QUANTA-Lyser® EIA/IFA processor, and NOVA View® digital IFA microscope.

2018 New Products and Highlights

→ The new Aptiva* system and reagents debuted at the 11th International Congress on Autoimmunity in Lisbon and the American Association of Clinical Chemistry Meeting in Chicago. Aptiva is a digital, multi-analyte system that dramatically improves laboratory workflow through the simultaneous detection of multiple analytes in a single reaction. Aptiva* also provides clinicians with access to the most comprehensive menu of clinically significant autoimmune biomarkers to improve the efficiency and confidence of diagnosis.



11th International Congress on Autoimmunity in Lisbon

“Aptiva is going to be a remarkable breakthrough in diagnostic immunology because it is going to start closing the gaps that we have had in diagnostic immunology for five decades. Both in terms of the coverage of antibodies that are unique and novel, it’s going to close the gap for clinicians who are complaining that some of the current assays are repeatedly negative. So we are all eager and looking forward to Aptiva.”*

Marvin Fritzler, PhD, MD, Professor of Medicine at the University of Calgary, Canada; Director of the Mitogen Advanced Diagnostics Laboratory

*Not available for sale. In development.

→ In the second half of 2018, Inova received clearance from the US Food and Drug Administration (FDA) for the QUANTA Flash HMGCR assay. Anti-HMGCR, a marker exclusively licensed by Inova Diagnostics, aids in the diagnosis of idiopathic inflammatory myopathy, a condition that results in progressive muscle weakness.

"HMGCR is the pharmacological target of statins, and a sub-group of our patients had experienced statin-associated myopathy. The presence of antibodies to HMGCR was found to be highly specific to myositis, and is associated with, but not limited to, statin exposure."

Andrew Mammen, MD, PhD, co-discoverer of autoantibodies recognizing 3-hydroxy-3 methylglutaryl-coenzyme A reductase (HMGCR), and Leader of the Muscle Disease Unit at the NIH's National Institute of Arthritis and Musculoskeletal and Skin Diseases



Aptiva* Digital Multi-Analyte System

In Vitro Diagnostics

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. We are consistently rated as a top-quality supplier, with over 80 long-term IVD industry customers who source immunoassays and biomaterials from us—in fact, six of the top-ten IVD manufacturers are our clients.

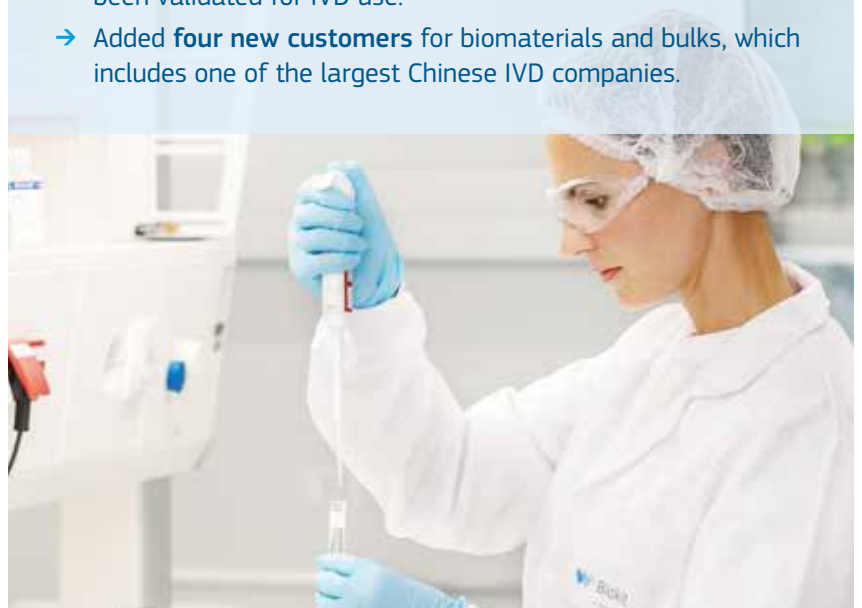
New Products & Highlights 2018

CUSTOMIZED ASSAYS

- Commercial launch of six **OEM Clinical Chemistry** assays and two **OEM CLIA** assays for a new platform of one of the top-six IVD manufacturers.
- Clearance from the **US FDA** of two **OEM CLIA** assays for a major IVD organization.
- Continuing development of six new **OEM CLIA** assays for two key OEM partners.
- **Prototypes and Proof-of-Concept assays** for Lyme disease and Parvovirus B19 for third-party companies.

BIOMATERIALS

- **Biokit** now supplies **four new biomaterials** for Instrumentation Laboratory and Inova Diagnostics. Additionally, six key assay components have successfully been validated for IVD use.
- Added **four new customers** for biomaterials and bulks, which includes one of the largest Chinese IVD companies.



Other areas of expertise reinforce our leading role in the field of IVD.

Clinical Software



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

New Products & Highlights 2018

- **Increased the number of software development projects completed from 14 to 16 annually.** This reinforces our position as software developer for Werfen, and thereby stimulates our commitment and passion for the development of state-of-the-art technologies. We are proud to help improve the quality of patient care and facilitate caregivers' day-to-day activities through our software initiatives.
- **Werfen affiliates' technical engineers from all over the world increased their knowledge of Werfen software solutions,** thanks to the Clinical Software Customer Support team who offered 14 training courses. Additionally, the Clinical Software Customer Support team produced several on-demand webinars for each software solution.



In Vitro Diagnostics

Clinical Chemistry

 **Instrumentation Laboratory**
A Werfen Company



ILab® Aries

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

New Products & Highlights 2018

- **Werfen in Italy** reached the leadership position in the toxicology market with 25% market share. This achievement represents a 12-year journey started in 2006, with the repositioning of the Chemistry Business Unit as a unique solution provider in the toxicology market segment.
- Clinical utility of **quantILab® Glycated Albumin**, an innovative assay for diabetes management, was successfully supported for the glycemic control of patients with type 2 diabetes mellitus at the change of the therapy. The Health Technology Assessment study coordinated by The Carlo Cattaneo University (LIUC), Italy, involved experts in Laboratory Medicine, Diabetes and Health Economics, resulting in a poster presented at the International Society for Pharmacoeconomics and Outcomes Research 2018 Congress in Barcelona.
- **ILab Aries** restyling project was successfully completed and field sites studies performed in Europe. Built on the experience from hundreds of laboratories worldwide, it offers enhanced efficiency with a state-of-the-art benchtop analyzer for small-medium-sized routine chemistry labs.

Infectious Disease Serology

 **Biokit**
A Werfen Company

Our experience in a variety of IVD technologies allows us to offer a wide range of high-quality immunoassays, from our company Biokit, that help Clinical Laboratories and Blood Banks improve quality of care and facilitate disease diagnosis for infectious diseases and rheuma markers.

New Products & Highlights 2018

- **Consolidated and growing sales of the HSV-2 (Herpes simplex virus type 2) rapid test in the USA.**

Medical Devices

Medical Devices accounted for 13% of total revenue for Werfen in 2018, with sales of 176 million euros.

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

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.



 **Leventon**
A Werfen Company

New Products & Highlights 2018

- **Dosi-Fuser reaches 100 thousand unit sales in one month** for the first time ever with more than 1 million Dosi-Fuser pumps produced in 2018.
- **Maintaining the market leadership with Dosi-Fuser in France** (with impressive growth in the High-Volume range) and Portugal. New therapies identified to maintain growth in those markets and many others.
- **Renewal of the contract with B Braun to extend our partnership** after more than 25 years for Dosi-Flow in the US market.
- **Dosi-Flow standardization phase completed**, representing a wider range for our customers, as well as the simplification of processes in our manufacturing facility.
- **Outstanding growth in our respiratory product lines, in both Spiro-Ball and Tri-Ball**, and entering new markets, such as Japan.
- Quality improvements to our Dosi-Fuser pumps; **manufacturing automation of Dosi-Fuser and customers training programs.**

Medical Devices & Scientific Instrumentation Distribution

We distribute both our own and third-party medical devices, such as disposables, orthopedic implants, and surgical instruments, as well as third-party scientific instrumentation.

New Products & Highlights 2018

- **Distribution agreement for Spain signed between Izasa Hospital and Phenox**, a company focused on solutions for the treatment of neurovascular diseases.
- **Izasa Scientific reinforced its partnerships** with leading companies in life sciences, such as Magritek and Fluidigm.
- **Medicinália-Cormédica consolidated its leadership position** as a distributor of Medical Devices in Portugal by achieving record sales in 2018
- **Nicolai signed a new distribution agreement with Asahi Intecc** for the distribution of its interventional cardiology and interventional radiology products.

Talent

Talent and Culture are the driving forces behind the short -and long-term success of Werfen. We harness this talent effectively by placing employees in the right roles with the right responsibilities, according to their strengths and preferences. This provides them proper direction and ensures they know how their actions contribute to our collective success.

We designed and implemented many frameworks in 2018 to create a positive work environment where our employees can bring out their best, to help them feel engaged, motivated and challenged on a daily basis.

Werfen Voices

In 2017, our Engagement Survey, “Werfen Voices,” allowed us to better understand the extent to which employees are motivated to contribute to the success of Werfen. In 2018, all people managers worked with their teams to design improvement actions to impact engagement in a positive way. We will repeat “Werfen Voices” in 2019 to calibrate the effectiveness of these actions and to better understand what and where we can improve as an organization.



Management Conversations

We continue to invest in our People Managers. Eighty percent of our Managers attended a “Management Conversations” workshop to increase confidence in conducting conversations with their direct reports throughout their career path at Werfen, from hire to retire. Topics of these conversations include management of expectations, driving engagement, providing effective feedback, and development and career paths. Overall, our managers were very pleased with this initiative, finding the content valuable and the facilitation extremely positive.





Talent and Culture are the driving forces behind the short -and long-term success of Werfen.



Reinforcing Communication

We have also improved our internal and external communication channels by revamping and upgrading our websites, increasing communication with all employees through messages from the President and CEO, reinforcing key messages related to the business and to our people.



Service Awards

Werfen is committed to appreciating and recognizing employee tenure, loyalty and commitment, and in 2018 we launched a Corporate Service Award Policy as a valuable component of our overall recognition efforts. This Award celebrates the years of service of our employees and highlights key employer contributions that have made Werfen what it is today.

Werfen Values

We also launched Werfen Values Worldwide, with each of our companies and affiliates celebrating "Value Day". Posters, leaflets and townhalls on our Werfen Values were the focus of the day in our offices around the world.



Talent

Why work for Werfen?

The strong values of our growing organization 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 key to our success. At Werfen, every person counts and can make a difference, and commitment, passion, and great results are recognized and rewarded.

Teamwork

- We share a collaborative culture of success
- Focused on goal achievement and long-term customer satisfaction
- Sales, Service, and Clinical Applications work in concert to support customers and their patients



"As a commercial organization, we are fortunate to have best-in-class products and the resources needed to succeed. We are focused on capturing the full value of our portfolio and are committed to represent Werfen Values in all that we do."

Bill Crandell
Director of Sales, North America
Instrumentation Laboratory

Customer Focus

- We are dedicated to improving the patient experience through our portfolio of innovative solutions
- Our culture is collaborative and can-do—working together to provide world-class support
- We actively listen to our customers' needs and wants, linking their success to our own
- A consistent emphasis on integrity and doing the right thing for the customer



"As part of the Inova sales force, I rely on teamwork and a customer focus from the organization.

This is at the core of what we do every day to close sales, implement Inova solutions into laboratories, and support our customers. The people and resources at Inova separate us from the competition and are key to our success."

Greta Bohney
Technical Sales Specialist
Inova Diagnostics

This is what our people say.

Development Opportunities

- Clear career roadmap
- Visibility of available jobs
- Mentorships with Senior Leaders
- Empowerment and accountability



"In less than two years at Werfen, I have been promoted twice. Werfen is a company that truly values and recognizes employees who exceed expectations, deliver results, are trustworthy and who apply Werfen Values in their day-to-day behaviors".

Qian Wang

VP Sales, China South
Werfen in China

Career Growth

- Professional and personal development for all employees
- Good opportunities for young talent
- International career opportunities at our companies and affiliates worldwide



"During my 14 years at Werfen, I have felt very empowered and trusted by our management to grow professionally and personally, and I am grateful for the many mentoring and exciting development opportunities. I am very proud to work for a company that trusts young talent with good career development opportunities".

David Giles

R&D Assay Development Director
Biokit

Quality Policy

Quality is one of the most important drivers behind Werfen success. We strive to meet the highest quality standards across all business lines and geographical areas, in compliance 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 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. All of our manufacturing facilities, logistics centers, and distribution companies around the world are certified with one of these standards.

Corporate Services at Werfen is currently implementing a Quality System based on the latest version of ISO 9001.

- Werfen in Colombia achieved ISO 9001 for commercial operations in 2018.
- Werfen in Iberia was successfully recertified in ISO 9001 in 2018.
- Leventon attained ISO 13485:2016 for Quality Management systems for Medical Devices in 2018.

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.

- Werfen in Iberia was successfully recertified in ISO 14001 in 2018.

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

MDSAP Certification

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

The MDSAP, enables medical device manufacturer compliance with standards and regulatory requirements in up to five different medical device markets: Australia, Brazil, Canada, Japan and the USA. The program's main mission is to "... jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

Werfen manufacturing facilities and products marketed in all these countries are MDSAP-certified.

Source: International Organization for Standardization, 2017 and FDA, 2018



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

International Registrations

Werfen products are registered with the respective authorities in a large number of countries worldwide, enabling marketing in these countries. Our manufacturing sites comply with country-specific regulations, such as: FDA (USA), CE (Europe), ANVISA (Brazil), NMPA (China), MFDS (South Korea), PAL (Japan), TGA (Australia).

International Healthcare Manufacturers Organizations

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

Werfen Quality Policy

Derived from our corporate values, this policy consists of the following principles:

- Marketing products of the highest quality, which employ the latest technology.
- Ensuring the needs of our clients are always met, and legal and regulatory requirements are fulfilled.
- Always keeping abreast of advances in technology to ensure state-of-the-art solutions for 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.
- Improving patients' quality of life through innovation.
- Encouraging our employees to live by these quality objectives.



Annual Report 2018



ABOUT US

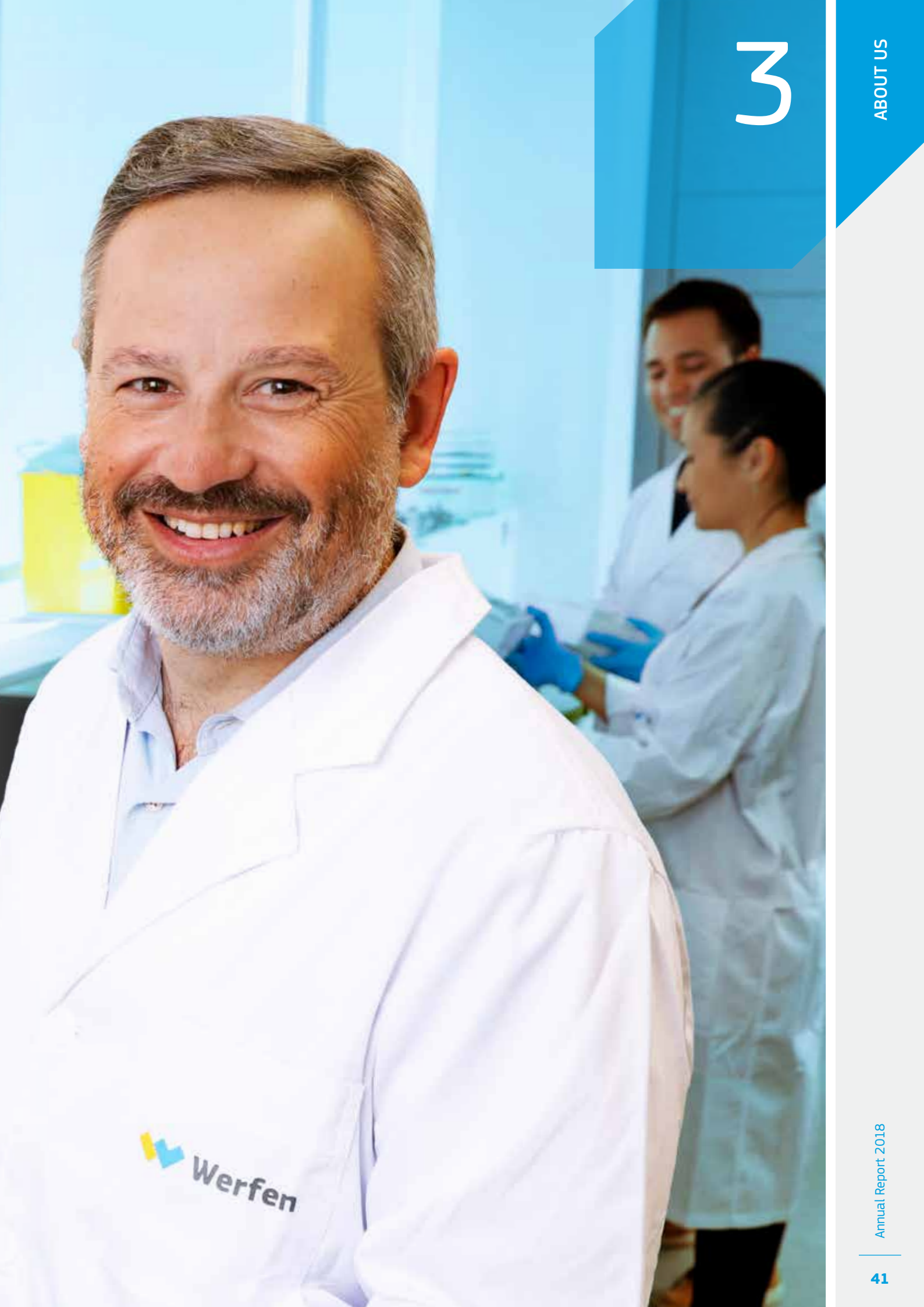
Governance

Citizenship

Milestones

2018 Highlights





3

 Werfen

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.

To ensure that strategic decisions are made in the interest of all stakeholders.

1 Marc Rubiralta

President

- Bachelor's degree in business administration, MBA
- 10 years at Werfen
 - 2 years in Finance Iberia, 3 years as Financial Director at Werfen in China, 5 years as President of the Medical Devices division
 - President of Werfen since January 2019

2 Jordi Rubiralta

Director

- Bachelor's degree in economics, MBA
- 15 years at Werfen
 - 8 years in several management positions in IVD and Medical Devices in Finance, and leading the European team
 - 7 years as President of Werfen

3 José Luis Rubiralta

Director

- Bachelor's degree in economics, MBA
- 13 years at Werfen
 - 4 years in Marketing Critical Care, Italy
 - 2 years in Financial Control, Italy
 - 7 years as responsible for Internal Audit and Compliance

4 Xavier Rubiralta

Director

- Bachelor's degree and Master of Biotechnology, MBA
- 8 years at Werfen
 - 4 years in R&D at Biokit
 - 4 years in Global Marketing IL in the USA

5 Carlos Pascual

CEO

- Bachelor's degree in law, MBA
- 31 years at Werfen
 - 4 years Director Operations in Clinical Lab
 - 5 years Director of Finance plus 10 years as Senior VP at IL in Italy
 - 6 years Senior VP IL worldwide except NoA plus General Manager IVD Iberia
 - 6 years as CEO at Werfen

6 José Luis Guerrero

CFO

- Bachelor's degree in business, MBA
- 17 years at Werfen
 - 15 years as Financial VP Worldwide IVD business in USA
 - 2 years as CFO at Werfen

7 Germán Castejón

Independent Director

- Bachelor's degree in business administration, MBA
- 20 years in banking sector
- Expert in Family Business

8 Lluís Cantarell

Independent Director

- Bachelor's degree in economics
- 25 years at Nestlé and member of the Board
- Expert in Health and Nutrition

9 Miquel Roca

Non-Director Secretary Director

- Lawyer
- Expert in Family Business

Governance

Executive Committee

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

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

Appointments and Remuneration Committee

This Committee is responsible to inform and assist the Board on issues related to Board composition, remuneration, succession plans and remuneration of first executives, as well as other issues related to remuneration policies and talent management, as requested by the Board.

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



The Werfen Code of Ethics establishes our commitment to ethical business practices.



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 they believe could contravene the ethics, legislation, or standards governing Werfen.

In 2018, 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 worldwide.

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, by continuously delivering the best solutions and services.

Supporting Employment

Community Affairs

For almost 30 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 have access to vocational training, as well as the opportunity to improve skills.

Through our collaboration with Fundació Portolà, Werfen has enabled 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 and greeting cards at our company offices
- Make and deliver rose bouquets on St. Jordi's day (the Catalan equivalent of Valentine's Day)

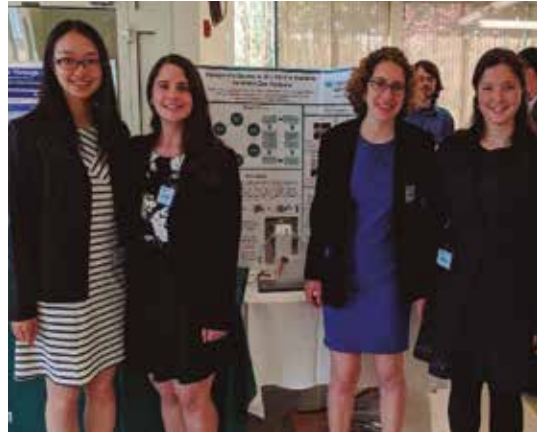
The economic contribution that Werfen makes to the foundation enables more than 100 people with disabilities to enjoy a place of work appropriate to their abilities, as well as enabling access to training courses and providing more opportunities for social integration.



University Capstones

Community Affairs

In 2018, Instrumentation Laboratory sponsored four “Senior Capstone Projects” for local universities in the state of Massachusetts, related to IVD. The students were from the University of Massachusetts–Lowell, Worcester Polytechnic Institute and Smith College. IL employees served as mentors to the students throughout the development of their projects. Upon completion, the students were invited to present their work at a poster session held at the IL main offices in Bedford. Their effort was inspiring and the guidance of the IL employees who worked with them invaluable!



STEM 2018

Volunteering

A group of IL employees in the Research & Development department ran a one-day Science, Technology, Engineering and Math (STEM) Camp for underprivileged teenagers during the summer of 2018. The team

introduced students to the latest technologies, such as the Internet of Things and wearable medical devices. The students learned a great deal, were inspired by the team, and had fun too.



Citizenship

Fundación Mencía

Community Affairs/Charitable

Werfen supported the Fundación Mencía, an organization that focuses on promoting scientific research projects aimed at finding a treatment or a cure for Genetic Diseases, especially rare diseases, which at present, are incurable and highly disabling. During the Christmas celebrations in Barcelona, Werfen organized a fundraising event, the proceeds from which, together with a private contribution from Werfen, were donated to the foundation.



Oncotrail Race

Volunteering

For the second year running, two teams from Biokit participated in the 6th 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.

The Werfen Ironman

Inspiration

Sometimes a Werfen team member achieves something incredible that inspires everyone. John Hill from the Operations team at Inova Diagnostics (Inova) did just that when he competed in the 2018 Ironman Triathlon in Kona, Hawaii. The Ironman circuit is recognized as one of the most grueling, physically demanding and mentally exhausting competitions in the world; comprised of a 3.86 km open water swim, a 180.2 km bike race, followed by a 42.2 km run.

Inspired by a father and son team who completed the Ironman together (with the father pushing his full-grown disabled son through the entire race), and wearing a specially designed Inova racing suit, John did his family, friends and all of us here at Werfen proud when he completed the course with a very impressive time of 10 hours and 20 minutes. John is a

reminder of the great people we have working here at Werfen and what is possible when you dedicate yourself to achieving great things!



Community Affairs
Charitable Giving
Inspiration
Sustainability
Volunteering

San Diego Blood Bank

Volunteering

Every day, volunteering blood donors help patients of all ages and conditions: trauma patients who have suffered accidents or burn victims, heart surgery and organ transplant patients, and those battling chronic illnesses, such as cancer. Inova partnered with the San Diego Blood Bank Foundation, who help save the lives of over 270,000 patients per year through blood donations. The Health and Wellness committee organized two blood drives in 2018, collecting more than 30 units of blood at both events, and plans to continue to support this important program in the future.

Social Contributions

Charitable Giving

Thanks to the generosity of Instrumentation Laboratory employees, coupled with matching donations from the company, a contribution was made to the Greater Lawrence Relief Fund (Lawrence, Massachusetts, USA) in support of employees and citizens whose homes and lives were disrupted by recent natural gas explosions. In December 2018, employees also contributed a significant number of new toys to “Toys for Tots,” a program run by the US Marine Corps Reserves, to provide holiday gifts to children in need.

Bio IQS Barcelona for iGEM 2018 Sponsorship

Community Affairs

Biokit sponsored a team of 13 Master of Bioengineering students from IQS School of Engineering (Barcelona) who entered the 2018 iGEM (International Genetically Engineered Machine), a competition organized by the prestigious Massachusetts Institute of Technology (MIT) in Boston. The aim of the competition is to push the boundaries of synthetic biology in tackling the everyday problems facing the world.

The team’s project focused on designing a personalized gluten sensor through a synthetic biology approach. To do so, they built a model, based on the Human Leukocyte Antigen (HLA) expression, which, when attached to a sensor, allows the detection of reactive gluten epitopes in patients.



Citizenship

Fundació Èxit

Community Affairs/Volunteering

Werfen partnered with Fundació Èxit with the aim of reducing the school drop-out rate among young adults. The organization helps socially vulnerable young adults by involving them in innovative and scalable training projects to provide them with valuable experience, deliver career path insights and improve their future employment opportunities. Werfen employees across a range of disciplines met with several young adults to offer guidance.

"Thanks to the project I continued with my studies and I had the opportunity to learn more about my strengths and abilities, which will help me face the world of work. I currently work in an NGO"

*Giorgi Perashvili,
Mentee from Fundació Èxit*

"For me, the coaching project means hope for the future..."

*Marta Amat,
Werfen mentor*

Creating a healthy and sustainable workplace in Can Montcau

Sustainability

Throughout 2018, at our Clinical Software facilities in Can Montcau (Barcelona, Spain), a group of employee volunteers worked tirelessly to foster healthy and environmentally responsible initiatives. Projects included: continuous and intensive education on appropriate recycling,

promotion of healthy habits, such as the "Be Healthy -> Be Responsible -> Be Refruiting" (fresh fruit snacks) project; and active coordination with Facility Services to fine-tune climate control and reduce waste.



Community Affairs
Charitable Giving
Inspiration
Sustainability
Volunteering

Commitment to protecting the environment

Sustainability

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 our dedication to managing our environmental responsibilities in a systematic manner and in compliance with international and local environmental regulations.



Supporting Education in Burkina Faso

In celebration of the 10th anniversary of Wend Barka Onlus (volunteer association founded by Werfen employees in Italy), Werfen in Italy launched "A school for children from Kolonguese" fundraising project.

The aim of the initiative was to finance the construction of an elementary school at the Kolonguese Village in Burkina Faso. Prior to this, the closest school for these children was several kilometers from the village—a journey

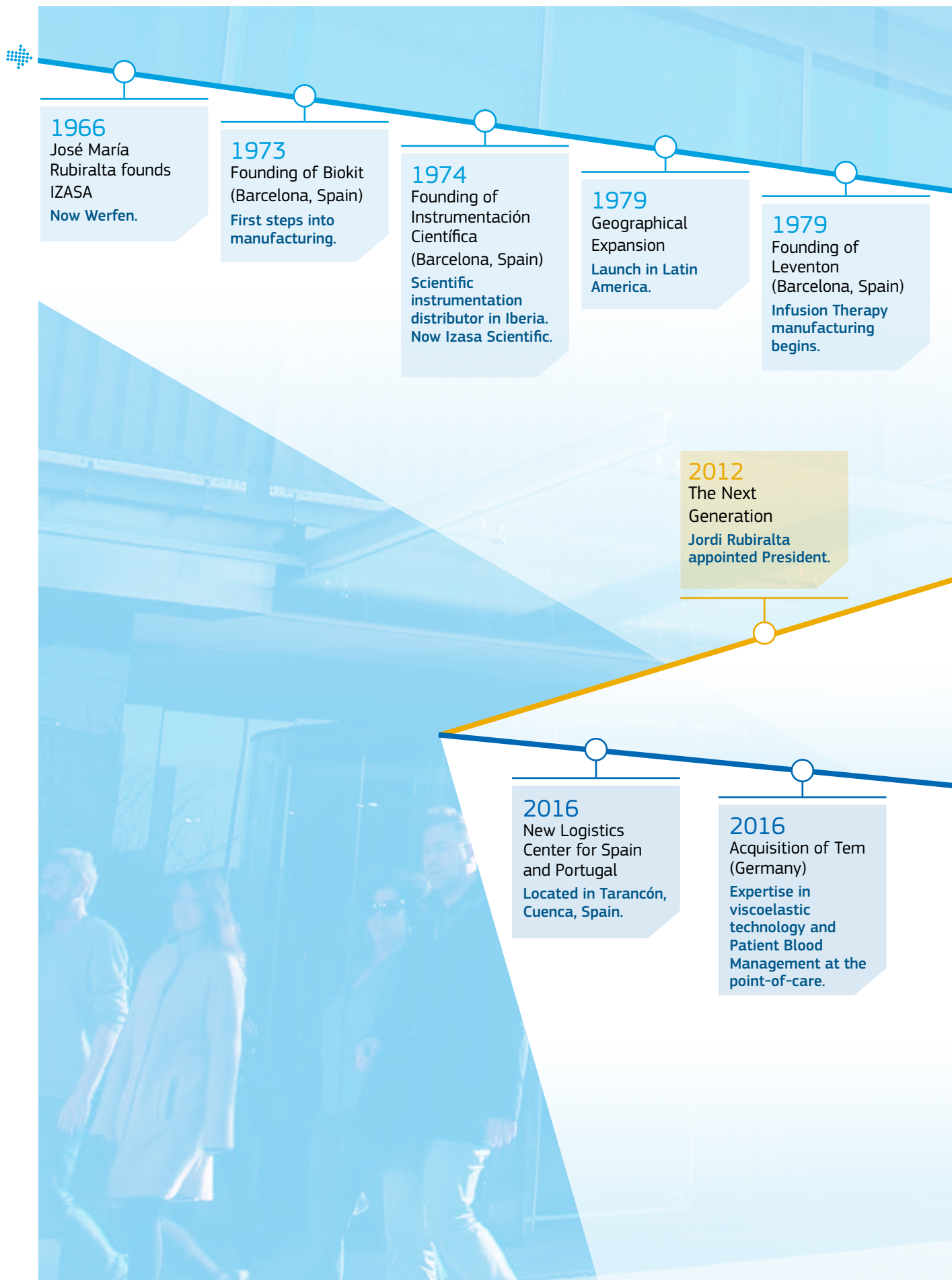
made daily. This obviously discourages children and their families from attending school, forcing children to work in the fields from an early age.

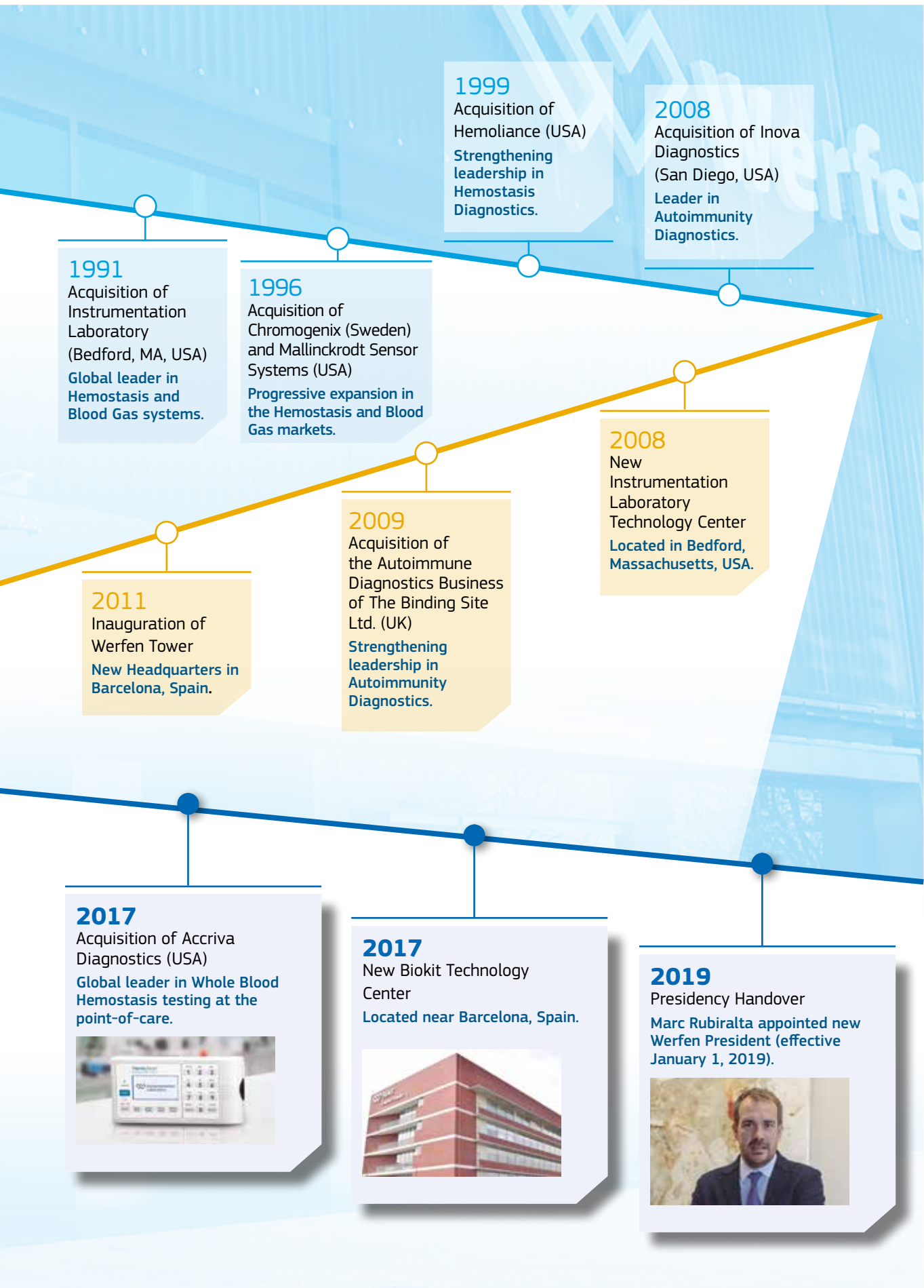
A generous donation was collected by Werfen in Italy and its collaborators. We are proud to be part of this success, which will have a significant impact on the lives of many children in Burkina Faso.



Werfen team and school children in Burkina Faso

Milestones





1991
 Acquisition of Instrumentation Laboratory (Bedford, MA, USA)
Global leader in Hemostasis and Blood Gas systems.

1996
 Acquisition of Chromogenix (Sweden) and Mallinckrodt Sensor Systems (USA)
Progressive expansion in the Hemostasis and Blood Gas markets.

1999
 Acquisition of Hemoliance (USA)
Strengthening leadership in Hemostasis Diagnostics.

2008
 Acquisition of Inova Diagnostics (San Diego, USA)
Leader in Autoimmunity Diagnostics.

2008
 New Instrumentation Laboratory Technology Center
Located in Bedford, Massachusetts, USA.

2011
 Inauguration of Werfen Tower
New Headquarters in Barcelona, Spain.

2009
 Acquisition of the Autoimmune Diagnostics Business of The Binding Site Ltd. (UK)
Strengthening leadership in Autoimmunity Diagnostics.

2017
 Acquisition of Accriva Diagnostics (USA)
Global leader in Whole Blood Hemostasis testing at the point-of-care.



2017
 New Biokit Technology Center
Located near Barcelona, Spain.



2019
 Presidency Handover
Marc Rubiralta appointed new Werfen President (effective January 1, 2019).



2018 Highlights

January

- Inova receives US FDA clearance for QUANTA Flash® Calprotectin

February

- Official Inauguration of the new Logistics Center for Spain and Portugal
- IL secures major Integrated Healthcare Network customer for Hemostasis and Acute Care Diagnostics

March

- Werfen in China launches its WeChat public platform
- 20-year anniversary of HemosIL D-Dinmer assay (IL)

April

- Werfen in Italy launches new website

June

- IVD recognized by World Health Organization as “Essential” to global health

July

- Inova launches new website
- ACL TOP Family 50 Series systems officially launched in China

August

- IL secures key US Patent to advance innovation in Blood Gas and CO-Oximetry testing
- Inova receives US FDA clearance for HMGR Antibodies Detection Test

September

- Werfen Values released worldwide
- Performance of Intelligent Quality Management (iQM®) on GEM Premier blood gas systems praised in leading Chinese medical publication
- Werfen in Germany moves to new offices

November

- Inova launches first Calprotectin Extraction Device cleared by US FDA

December

- Marc Rubiralta appointed Werfen President (effective January 1, 2019)

2018

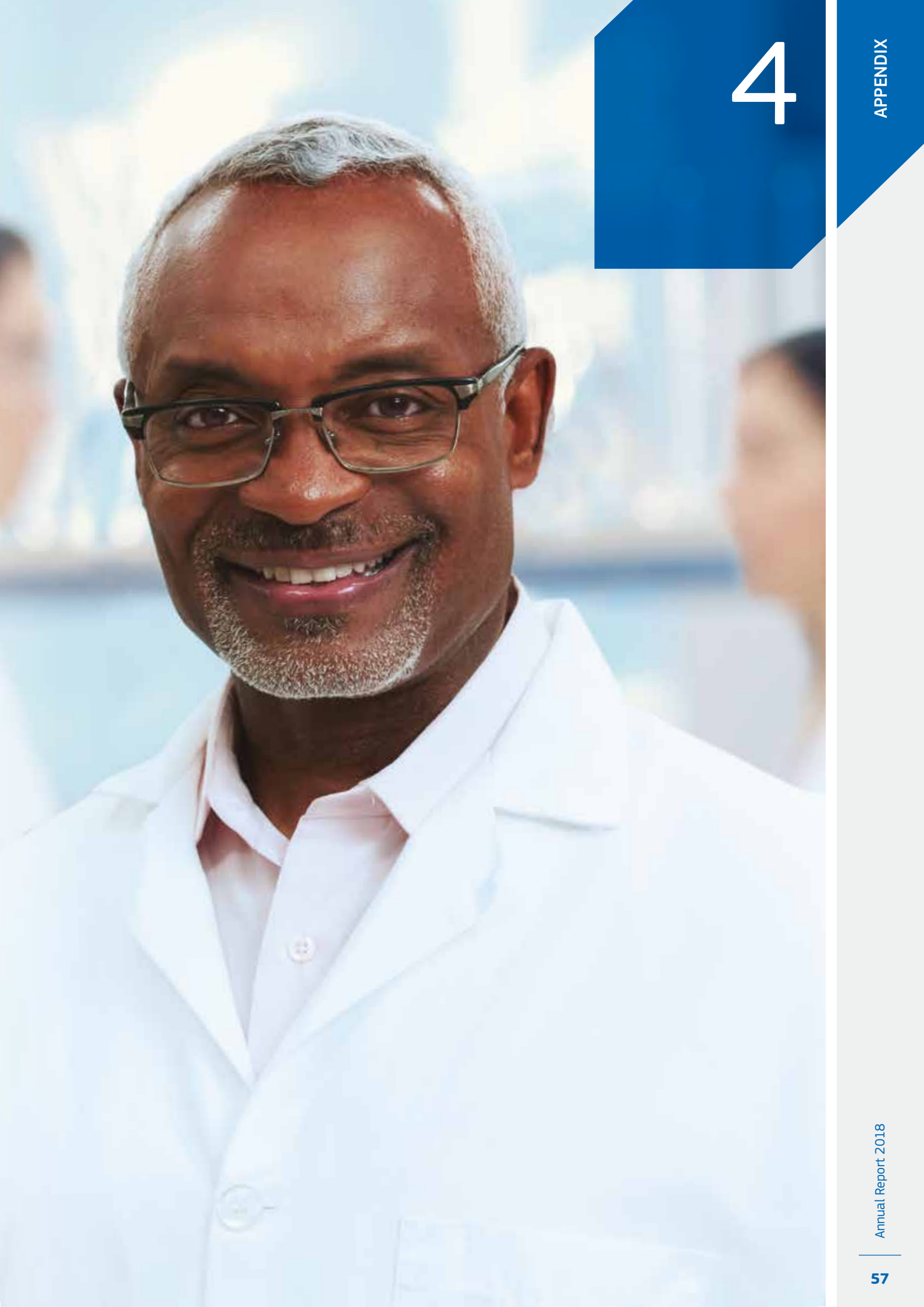


Annual Report 2018



APPENDIX

Glossary



4

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.

Autoimmunity

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

Calprotectin

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

Chemiluminiscent (CLIA) assay

Based on an 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 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 maintain 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 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) testing

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.

Original Equipment Manufacturing (OEM)

Offering products and services to other companies.

Rapid tests

Diagnostic tests used 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.



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[werfen.com](https://www.werfen.com)