

The following report was created by Global Business Reports, a European research firm that develops reports for a number of industry sectors. This particular report offers a look at our neighbors to the south and their health care industry. I welcome comments on this report as well as any input on other countries or regions you'd like to see covered in DOTmed Business News.

*Sean Ruck, editor-in-chief, DOTmed Business News*



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This report was researched and compiled by Global Business Reports ([www.gbrreports.com](http://www.gbrreports.com)) for DOTmed Business News.



Special Section:

# An analysis of Mexico's health care manufacturing sector

## The Mexican Medical Devices Sector

With roughly 113 million inhabitants, Mexico is the third most populated country of the Americas and the fourth highest in terms of total GDP (purchasing power parity). In terms of the utilization of health services, according to the World Health Organization (WHO) Mexicans enjoy sound health coverage, with an average utilization of health services that is above the regional figures. Based on the WHO's data Mexico's investment in health services accounts for 6.5 percent of its total GDP, representing about \$846 per capita, one of the highest amongst Latin-American nations.

The steady growth of Mexico's population, the increasing incidence of cardiovascular and other chronic afflictions, and the rising public and private investment in health care infrastructure are all factors contributing to the development of the medical devices market in the country. During the period 2003 to 2010 the Mexican health industry grew at an annual rate of 11.4 percent. According to the Mexican national statistic body, the National Institute of Statistics and Geography, the manufacturing of medical devices in the country reached a total value of 5.066 billion dollars in 2009, providing employment for 100,000 Mexicans. According to data from the Mexican Secretariat of Economy, the foreign direct investment on the sector stretched to 927.5 million dollars from 1999 to 2010. "Mexico is well established as a manufacturing centre for medical equipment, said Giovanni Sierra, business development and sales director of Alandra medical, a Mexican company that focuses on medical trials and medical device development. "In fact, if there are two manufacturing sectors well developed in Mexico, they are aeronautics and medical devices." The strength of the country's medical devices industry is attested to by the vast presence of international companies.

The massive presence of foreign medical devices firms in the country can be explained by various key

factors. In terms of production costs, Mexico is one of the most competitive countries worldwide. According to a study from Alix Partners, while manufacturing costs for the medical devices industry are six percent lower in China than in the U.S., the average cost of producing in Mexico is an impressive 25 percent less than the cost to produce in the U.S.. Moreover, Mexico is one of the most open economies to foreign trade in the world; its foreign trade accounts for 58 percent of its GNP and for 40 percent of Latin-American international exchanges. Indeed, through more than 40 free trade agreements (NAFTA being the best known) Mexico has direct access to a market of more than 1 billion consumers representing 68 percent of global GNP. It is no surprise

that the World Bank (in the Doing Business 2012 report) ranks Mexico as the sixth most attractive country in the region for foreign investors. The absolute respect for international standards on intellectual property rights, added to the excellent preparation of its medical professionals and engineers and the importance

of its home market, put the finishing touches on the position of Mexico as an ideal location for the development of the medical devices' industry. Today, the country ranks fifth in global export of medical devices.

The dynamism of the Mexican market has made it an ideal location for corporate expansion. Nevertheless, Mexico still offers far more investment opportunities in the productive side of the business chain. Foreign companies, especially American ones, have heavily developed their productive capacities in the country, thus benefiting from the relatively cheap labor costs, the advantageous cost competitiveness ratio and generally from the maquiladoras' system - a series of free-trade areas usually located along the Mexican-American border where factories import material and equipment in a duty-free basis.

Mexico's proximity to the U.S. and the NAFTA agreement are considered simultaneously a blessing and a curse for its medical devices industry. On one hand, it has fed the development of the Mexican industrial



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infrastructure. On the other hand, it has hindered the development of strong international companies in the sector. “The close proximity of Mexico to the U.S. has made it easier and cheaper for Mexico to buy equipment from U.S. firms rather than to develop its own equipment here,” says Juan Pablo Dovarganes, general manager of Arroba Ingeniera, a Mexican developer and producer of equipment for newborns.

In the case of Mexican distribution companies, suppliers are predominantly located in the U.S., as it is easier for them to do business with their northern neighbor given both the geographic proximity and the different trade and equivalence agreements between both nations. Nevertheless, Mexican distributors’ general dependency on U.S. suppliers has a consequence. “One delicate factor related to Mexican dependence to U.S. suppliers is that our business performance and our competitiveness is very sensitive to the fluctuation of the U.S. dollar,” says Mario Rey, commercial director of Alrich Medical, a Mexican distributor of medical equipment. “As a matter of fact, last year was harder than usual given the revaluation of the dollar compared to the Mexican peso, and this has had an impact not only on medical device distributors but also on the health care sector as a whole.”



## The Mexican Health Sector

In Mexico, the public health sector is complex and fragmented into diverse institutions. The Instituto Mexicano de Seguridad Social (IMSS) provides for the registered employees from the private sector, while the Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE) does its part with the Mexican civil servants. Meanwhile, the Defense Secretariat as well as the national oil company, PEMEX, have their own health systems. Finally, every Mexican without access to any of the prior-mentioned institutions has the right to the Seguro Popular (Popular Insurance), a recently created plan providing health assistance to underserved Mexicans. Ramiro Gago, General Manager of Casa Plarre, the main Mexican manufacturer of anesthesia machines, underlines the importance of the introduction of the Seguro Popular: “the Seguro Popular is a reaffirmation of the fourth article of our Constitution, granting all people protection to their health. With this plan, the scope of the protected population has greatly increased, bringing the Mexican health system closer to a universal coverage.”

As a whole, the Mexican health system is regulated by the Health Secretariat, which is responsible for the establishment of the main guidelines of the Mexican health policy and the National Health System. As such, the Health Secretariat has to ensure public and private institutions act in accordance with national health regulations and policies.

The Mexican health sector is predominantly public; nonetheless, the private sector has steadily increased its share. In the last decade, there has been an increasing interest in the private sector, with the exponential growth of private health groups such as Grupo Ángeles, Médica Sur, Hospitales ABC and StarMedica. The predominance of these private groups has pushed smaller private health institutions to cooperate and join efforts in order to increase their leverage when negotiating the acquisition of medical devices with distributors and manufacturers and to attract new patients while under the shadow of those giant private groups. A good example of these cooperative relationships can be seen in the Consorcio Mexicano de Hospitales (CMH), the most important private network of hospitals, with 27 associates throughout the Republic, and initiator of a plan that has proven its worthiness by improving the quality of its associates’ services and their negotiating strength with providers and insurance companies.

The future perspectives on the evolution of Mexican medical systems look bright. Though the private sector had a hard time in 2009 and 2010 due to the international economic crisis that impacted the country, it has greatly recovered and is expected to grow steadily in the coming years. Alejandro Paolini, General Manager of Philips Healthcare, backs that assessment. “The private sector

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had a hard time in 2009, but it has improved and is now moving along with the industry. The public sector can change and it is hard to predict should there be a change of government, but things look good, and the current government is investing a lot into the health sector," he says. (Editor's note: Since the completion of this research, the government the PRI's victory in the recent presidential election will mean a change of government). "We do not predict the political climate here in Mexico to change very much soon. It is heading along a good path and should continue to do so. Universal Health Coverage is something of great importance to the current government and it looks set to continue on its path towards widening in the country. In the worst of cases, Mexico will maintain its current levels of investment in the health sector, but it is very likely that these will increase."

**Factors shaping health care**

There is the understanding that prevention is better both for patient health and for budgets than providing cures. This, added to the need of ensuring universal health

coverage, will require an increase in the government's investments in the health sector. These perspectives on the future evolution of the health sector's resources and the recognition, both public and private, of its importance are undoubtedly good news for the local medical devices industry.

On the future of the public and private sector, Arturo Garza, Executive Director of Medicus, a Mexican innovative integral services' provider specializing in the field of anesthesia, says, "My belief is that the public and private service will [work] more closely together. The private sector has more beds than they need, so it makes sense for them to unite with the public sector. Some public clinics are already hiring private clinics for services and beds and I am sure this phenomenon of increasing synergies between the private and the public sectors will intensify in the near future."

Another prospective evolution already affecting the Mexican health institutions is medical tourism. Substantial investments are currently being made: developing new technologies, bringing in new health professionals

and creating new facilities in order to meet the needs of medical tourists. “Mexico has the structure and the means to position itself strongly in this sector of health internationally,” says Milton Rosario, former President of the Mexican Association for Innovating Industries in the Medical Devices Industry (AMID).

It’s predicted that medical tourism will grow exponentially during the next decade.

## Regulatory concerns

Concerning the regulatory framework structuring the Mexican medical devices industry, there is a major flashpoint. The substantial challenges in registering new products for production and distribution in the country often prove too daunting for fledgling companies. This registration process, which is indispensable for the distribution of medical devices, is responsibility of COFEPRIS, the Mexican equivalent of the United States Food and Drug Administration. The problem is that bureaucratic procedures and requirements concerning the registration of medical equipment and devices are slowing down the arrival of the latest products to the Mexican market, with the exception of those classified as “low risk” or 1A Class by COFEPRIS. There is no doubt that, given its role, the health care industry has to be tightly regulated, yet the registry is so delayed due to a backlog of registration petitions that the wait for review averages one year, while in some cases, the wait can take more than two years. “This has had, and still conveys, a negative effect not only on distributors, but also on the health system as a whole and ultimately on patients,” says Mario

Rey, Commercial Director of Alrich Medical Services, a Mexican medical devices’ distribution company. “Given that as a result of the regulatory obstruction, they cannot enjoy the latest medical technologies because of the difficulties related to their registration by the COFEPRIS.”

Although there continues to be delays, steps are being taken to reduce them. Much of the progress has been helped by AMID’s intercession. AMID was founded in 2007 to form a united common front in order to help authorities to improve the sector’s regulatory framework.

Another factor that has greatly contributed to the disentanglement of the delivery of registration certificates was the appointment of Mikel Arriola as COFEPRIS’ Federal Commissioner in March 2011. Within one year, he has revolutionized the way the COFEPRIS works and has greatly improved its efficiency. “With the new COFEPRIS commissioner things have improved a lot,” says Alfredo Merino, general director of Fresenius Mexico. “With the past commissioner, all sanitary registrations were kept on hold. Today, everything is moving much faster as the new commissioner is working very closely with the industry.”

The changes made have all been in line with the global harmonization task force, which aims to harmonize national medical devices’ regulatory systems around the world. The most relevant innovation has been the equivalence agreement, also known as “fast-track”, signed in October 2010 between Mexico, the U.S. and Canada, easing the registration processing of products already approved by the FDA or Health Canada. The fast-track signed in 2010 with the U.S. was decisive given the importance of U.S. companies and products in the

Mexican medical devices market. “St. Jude Medical was the first company to benefit from the fast-track plan,” said Ramón Soto, general manager of St. Jude Medical in Mexico. “This first time the process took only 10 days. It constitutes a great enhancement compared to the conditions existing prior to the signing of the agreement.”

In January, those agreements were expanded to include Japan and are expected to be extended to the EU fairly soon. The new framework has drastically reduced the time necessary to get a medical device officially registered. Makoto Kato, General Director of Omron, a Japanese international company specialized in cardiologic devices, praised the benefits that will be brought by the recently signed equivalence with Japan. “Omron, as a member of the Japanese Chamber

**Giovanni Sierra, Business Development Manager, Alandra Medical.**



of Commerce, has been supporting COFEPRIS during the negotiations with the Japanese Health Authorities. We are very optimistic with this fast track agreement as it embodies a decisive stimulus for the growth of Omron's business in Mexico," he said.

### International players in the Mexican market

The recent expansion of the Mexican market for medical devices enlarges opportunities for foreign corporations in this sector to begin or increase their business in the country. Imports are assessed to signify 70 percent of all purchases of medical devices and the U.S. has been the foremost purveyor with around 65 percent of market share. There is growing interest in the Mexican market and this falls under a general focus toward Latin American markets. Aldo Montes, country business manager for AGFA HealthCare Mexico, confirmed this general trend. "Latin America did not represent an important part of AGFA's global business 20 years ago," he said. "Today this region signifies 17 percent of our global business."

Experience has shown that in order to thrive within the Mexican medical devices marketplace it is not sufficient to simply import products from foreign markets and distribute them in Mexico through third party distributors. Indeed, given the size of the Mexican market, many international companies have decided to establish themselves in Mexico. Omron success' story in the Mexican market exemplifies the advantage provided by a direct presence in the country. "Citizen and Microline are our biggest competitors; however we have a clear advantage over them as, not having a direct presence in Mexico,



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**Francisco Jaramillo,**  
Managing Director,  
FJBiomédica

they have to work through intermediaries,” says Omron’s general manager, Makoto Kato. “The benefits of having offices here have been reflected in Omron’s results: we opened our Mexico office two years ago and since then our market share has grown from 25 percent to 48 percent today.”

Omron is not the only example of an international company reaping the benefits of a locally based office. Since 1992, International Medical Service distributed the products of St. Jude Medical in Mexico. However, three years ago St. Jude Medical decided to transform International Medical Service to an official branch in the country, keeping its resources and employees, including general manager Ramón Soto. Soto acknowledges how the transformation has provided for a steady growth for St. Jude Medical’s business in the country. “Before as distributors, we did not have access to all of St. Jude Medical in the country. Now we do, and we also have more flexibility in our prices. The benefits are so tangible that during the last three years we have been growing at a 20% yearly rate,” he says.

Fernando González, general manager of Welch Allyn Mexico, reinforces the idea of Mexico as a thriving

market worth investing in. “Mexico poses a wealth of opportunities, both in our ambulatory care segment, which is the line we are most well-known for, but also in the acute care segment, which includes the up and coming clinics and government hospitals which are in dire need of improving and enhancing technology, and as a result, improving the patient’s experience in the hospital,” he said. “Welch Allyn has for a long time seen Mexico as a country of great opportunities. With our Mexico team, we can more closely align with end users in order to deliver the products they need.”

Alejandro Chávez, former country manager of GE Healthcare in Mexico, testifies on the importance of Mexico as a manufacturing destination: “we primarily began importing goods from the 1940s onwards to the 1980s during which time we established a large-scale office in order to sell locally. We have since constructed two manufacturing plants, one in Ciudad Juárez and the other in Monterrey. Indeed, Mexico is the country that has the most production plants outside of the U.S., which says a lot about the importance of the country for GE.”

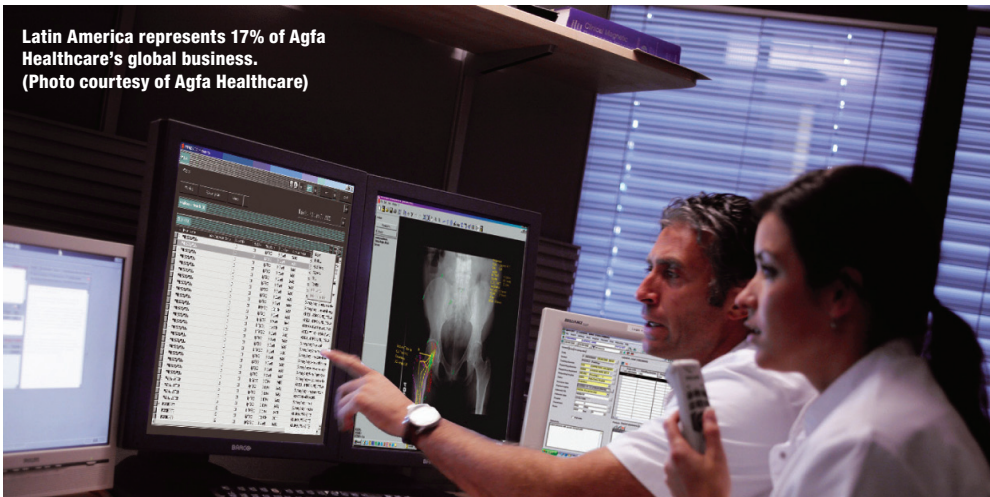
Manufacturing activities in Mexico provide an important part of its total production for U.S. company Becton Dickinson. The first BD factory in Mexico, opened in 1957, was also its earliest factory outside the U.S. “In Mexico, BD has evolved towards the manufacturing of a wide range of products and we have many production plants in the country,” says Kurt Wicker, general manager of Becton Dickinson in Mexico. “We are very proud of having created a thousand jobs in the past two years, reaching a total of 3,500 employees in the country.”

Medical devices produced in the country by international companies are mainly allocated for export. Nevertheless, national demand is also an important incentive for productive investments in the country. Alfredo Merino, General Manager of Fresenius Medical Care, Mexico, backs this thought. “We bought the current manufacturing plant in Mexico, since the amount of demand from the Mexican market required us to increase production. We manufacture peritoneal dialysis solutions; some of the products that we manufacture here are exported to the U.S., but the majority are for the Mexican market.”

Many growth opportunities have appeared within the national market for those companies offering solutions to chronic diseases that are increasingly affecting Mexican population; in some cases reaching epidemic rates. One of the fields that have attracted more resources from the government in the past few years and will continue to do so is the fight against obesity and diabetes. Merino points out how Fresenius is helping to fight those problems, not only through their dialysis solutions, but by working with the health administration to improve

Kurt Wicker, Director General, BD





Latin America represents 17% of Agfa Healthcare's global business. (Photo courtesy of Agfa Healthcare)

from the government; hemodialysis is a very expensive process and many patients cannot afford it, so the government should pay for it. We are working to have a universal health service for hemodialysis.”

Welch Allyn's González seconds the need to focus on chronic disease as a crucial portion of health care in Mexico. “The ability to manage a patient's disease is crucial, and

public coverage for this range of diseases. “Today, there is a very severe problem with obesity and diabetes and, in the medium term, this will have an impact on kidney diseases,” he explains. He says that those in the lower financial classes not covered by the IMSS or the ISSSTE are facing a major problem. They do not currently get free access to hemodialysis through Seguro Popular, with the government citing lack of funding to support that type of coverage.

“The government has a lot of work still to do; we have huge obesity rates, including child obesity, and the government must act against this, since around 70 percent of obese people will require hemodialysis,” Merino says. “There is an important challenge which is government spending. There is a definite need for more investment

if one does not have or invest in the proper technology to do so, it is very hard to be successful,” he says. “The physician needs to have the necessary tools to manage these diseases. One of the most important aspects is reliable vital signs data, clinical information available in the patient's health record, and proper information for the patient's care. This is a key element in our business proposition. We truly believe that by employing technology in the vital signs field, and sharing or transmitting that information onto a clinic health record the health care industry will be able to properly manage these chronic diseases that are ailing our country.”

Omron's Kato stresses the importance of education and awareness-raising campaigns for fighting chronic diseases related to cardiologic and arterial affections. “In



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contrast with other markets, in Mexico there is an alarming lack of consciousness on the importance of keeping a constant track of cardiologic variables. It is very important for Omron to work in enhancing awareness on that sense. Omron Mexico launched, in cooperation with Mexico's City authorities, 'Corafest,' a campaign offering free blood pressure measuring and informing Mexicans on the importance of monitoring their blood pressure and cardiologic variables."

Other than the traditional companies coming from the U.S., Europe and Japan, in the last decade Chinese companies have begun to penetrate the Mexican market with encouraging results. Concerning this arrival of Chinese devices, Elia González Murillo, managing director of Ingeniería y Sistemas Electromédicos (ISE), one of the main medical devices distributors in the country, working with such companies as Hill-Rom and Trumpf, stressed that there has been some reticence towards Chinese devices, but the quality of the products provided by some Chinese companies has been greatly improved during the last years. "However, their way of approaching the market is not in accordance with our standards," she says. "They do pressure too much for low prices and at

the same time their products usually do not have a long life expectancy and they do not value long-term relationships enough. This idiosyncrasy from Chinese producers is in contrast with ISE's way of approaching the market, as for us the most important goal is offering high quality products and keeping a close relationship with our partners and clients."

Other than new equipment, remanufactured equipment constitutes an expanding market for international and Mexican companies. Francisco Jaramillo, managing director of FJBiomédica, a Mexican distributor of remanufactured equipment, working with ANDA Medical, a Canadian international company providing refurbished medical equipment with the highest quality standards to the medical community worldwide, explains this partnership: "Today, FJBiomédica and ANDA Medical have an exclusivity agreement. All ANDA Medical equipment sold in Mexico is distributed by FJBiomédica. FJBiomédica offers high quality refurbished equipment, maintenance services and parts to hospitals and clinics throughout the Mexican Republic. Indeed, our remanufactured products offer great advantages: they come from the best medical equipment brands and combine a high and

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### Local players: towards the development of a solid national industry

Today, there are few national producers of medical equipment in Mexico. The national industry is not developed, due in part to a lack of government incentives and solid competition from foreign producers. Indeed, if compared with the Brazilian medical devices national industry, able to produce sound quality products competing against imported devices, the Mexican industry appears to be barely more than a niche sector.

One of the differences that explain this mismatch is that, while Brazilian authorities have limited or taxed the import of foreign devices, Mexican authorities embarked on successive free trade agreements opening its market to foreign industrial production, including in the field of medical devices. This has had good results in increasing trade and attracting foreign capital but has also hindered the development of the national industry.

Diana Reyes, General Manager of Grupo SIM, a Mexican local manufacturer and developer of high quality medical devices for life support, specialized in medical

ventilators, brings her point of view to this issue. “I think that the Mexican medical devices industry has huge possibilities of future development: today it has not even attained 20% of its full potential. One of the problems is that in Mexico, usually, we do not believe in ourselves nor in our products. Even national authorities mistrust Mexican articles. Paradoxically, they provide national companies with funds to support product development but once developed are reticent to acquire those products. This mistrust is the worst enemy for the national industry. For a Mexican company to be trusted nationally, it has first to succeed internationally, and that is exactly what Grupo SIM is going to do: we have ISO 9000 and FDA certificates and our objective is to distribute our equipment in the U.S.”

One of the clear problems accompanying lack of development of the national medical devices industry is the lack of innovation and product development. “I would personally like to see more innovation within the country, but sadly we are facing a scenario here in Mexico where young professionals prefer to work outside of Mexico and, if they do work in Mexico, they prefer to work for large multinational companies such as Siemens and Philips rather than working for Mexican companies. This supposes a clear obstacle for innovation,” says Arroba Ingeniera’s Dovarganes

“There are still very few medical products that are developed here in Mexico,” he says. “Only a few Mexican companies develop medical equipment, compared to 50 or more [Brazilian] companies developing medical equipment in Brazil; a quite appalling situation considering that Brazil and Mexico have comparable economies,” Dovarganes says.

On this line, ISE’s González Murillo, stresses the fact that, “Mexican companies have focused too much in

servicing the lowest end of the market, with very basic and simple products, but have totally neglected the middle and highest ends of the medical devices' market. There is a problem shaped by the lack of technological transfers that like in the case of Brazil, could have hindered the development of the medical devices' national industry; likewise there is a certain lack of ambition and confidence from many national medical corporations."

This does not mean that there are not local creative companies devoted to product development in the field of medical devices. Alandra Medical is a Mexican firm devoted to research and development of medical devices and clinical trials. Giovanni Sierra, the company's business development manager, talked about the future of medical devices' research in the country. "The development of new technologies for medical devices is a very expensive process; that is why we work with the Secretary of Economy and CONACYT who help us to raise the necessary resources to fund our projects in the development of new products. It is important to note that globally, with the 2008 financial crisis, the investment for the development of new medical devices was decelerated. Today, there is a huge interest in this field. Indeed we can say that today the medical devices industry is attracting more attention and resources than

the pharmaceutical industry. This is due to the fact that having experienced impressive advances in the last decades, the pharmaceutical industry is now mature and it is difficult and expensive to find innovative formulas."

Other Mexican local companies have been focused in providing services to the industry and to the health care sector to allow the smooth functioning of the market. This is the case of Finamed; its general manager, Juan Carlos Torres, explains how this innovative and quickly expanding company has contributed to distributors' operations and the provision of medical clinics and hospitals. "Medical equipment is very expensive and most people are not able to pay in cash. And it is difficult to apply for credit in Mexico since many people are paid in cash and therefore do not develop a credit rating or history with official financial institutions. Finamed addressed this problem with an innovative way to grant credit. We take into account all of a person's assets; liquid and physical assets, their reputation, involvement with the society, associations they may be involved with, among others. We do leasing and this acts as our guarantee. Medical equipment has a long life and since we are leasing we are guaranteed to make our profit."

● Online: [dotmed.com/dm19166](http://dotmed.com/dm19166)



Alejandro Paolini, General Manager Healthcare, Philips.