

X-halo

by D E L M E D I C A

Breath Thermometer
for asthmatics



product
design
award

2008

PRESIDENT'S
DESIGN AWARD
DESIGNER OF THE YEAR 2009

Marking New Territories

ISO and CE accreditation granted

Delmedica Investments Singapore Pte. Ltd (DMI) has secured its ISO 13485, ISO 9001 and MDD CE certification for X-halo.

Its procurement is a significant one.

Jas Gill, Managing Director explains: "As symbols of high operational and product standards, they [ISO and CE marks] finally allow us to mass market the device throughout the EEC and other regions around the world."

ISO and CE marks will enable DMI to reach, and reassure, a cautious but ultimately receptive end-consumer, through direct sales and new distributorships.

"As with all new and revolutionary products, establishing brand and product trust is a fundamental part in any decision-making and purchasing process. This applies as much to a potential distributor, retailer or government body as it does the general public."

These certifications effectively announce that the company's procedures as related to design and development, production, logistics, quality controls and accountability are firmly in place.

"These marks add incredible value in our negotiations with distributors, retailers, the medical industry and its professionals. Their adoption will be carried throughout all future media, marketing and packaging."

FDA Signs of Approval

DMI has also filed its application to the FDA for 510K accreditation. This will allow the company to access what is considered the largest, and most accessible, market for X-halo.

FDA approval is expected within the next 4 months.

New National Charters

X-halo is currently being registered as a Class 2 device for Italy and the ASEAN nations, including: Indonesia, Malaysia, the Philippines, Singapore, Thailand, Cambodia and Vietnam: Nations, many of which are rapidly developing, that represent over 8.7% of the world's population.

Other registrations will follow as distributors are appointed.

Patent Proof

DMI secures protection within 37 countries

DMI is pleased to announce the granting of its patents, by the European Patent Office, for its innovative X-halo technology.

Neil White, Director DMI: "It's a defining and exciting phase in our development. It enables us to push forward... it sends a message to the industry, our partners, our distributors and, of course, the consumers that what we have is not only unique – but highly protected."

The US and Japan patents remain under review but are expected to meet with the same approval.

More Visual Presence

DMI launches its new Website and Marketing Material

The new website is now live and contains all the latest information related to DMI's activities. It features a library of past particulars and the release of a new wave of marketing collateral, including: print literature, product data sheets, management algorithms and updated instructions for X-halo use.

DMI are also currently working on a software update designed to facilitate a better user experience. This will be available, as a downloadable firmware update, from the middle of September.

Upcoming Tradeshows

DMI will showcase its X-halo product at the European Respiratory Society (ERS) meeting in Barcelona from September 19-22nd, 2010.

20,000 pulmonary and respiratory physicians are expected to attend. DMI will also present 6 abstracts over the duration of the event, highlighting the clinical trials and positive results that have been undertaken using the X-halo technology.

DMI will also attend the Medica Trade Fair in Dusseldorf in November, 2010.



New Distributorships

Sensormedics Italia Spa have been appointed as our Italian representative, effective 1st August, 2010.

DMI have already concluded a comprehensive program of training, product orientation and data sharing with the group's sales and marketing departments.

The trip to Italy also included a series of meetings with some of the nation's leading pharmaceutical companies and; representatives of frontline physicians organizations. The positive outcome is expected to culminate in significant orders of X-halo throughout Q3 and Q4, 2010.

Other distributors will be appointed during the ERS and Medica tradeshows later this year.

Senior Appointments

Richard Lockey, Chairperson Chairman of USA Scientific Advisory Board

Professor Lockey's credentials are impressive and include senior positions held in educational and medical echelons throughout the United States.

Widely published, Dr. Lockey has authored, co-authored or edited over 500 literary pieces and served as speaker to hundreds of national and international scientific conferences.

Widely regarded as a leading authority on Allergy and Immunology he is also a practicing physician and active member of several renowned medical societies, associations and task groups.

Amongst these is his ongoing work related to the long-term research into treatments for allergic diseases and asthma. He has also proved instrumental in the raising of funds required for such initiatives.

Mr. Lockey brings to DMI considerable experience, knowledge and leverage within the medical sectors, particularly in relation to X-halo's field.

His endorsement and support of X-halo and its team serves as a powerful anchor point for the future of DMI.

Yeo Boon Hon, Director of Operations

Mr. Yeo brings to the table over 20 years of expertise within the realms of research, development and manufacturing.

Having studied at the National University of Singapore, his BoE honours and impressive management and operational record make him a valuable acquisition for DMI.

"My primary focus will be to build upon an already well-established production framework... fine-tuning issues of cost, design, quality, operational efficiency and a further consolidation of computer integrated manufacturing."

Yeo has, in recent years, levitated towards the Bio-Tech arena; spearheading the procurement of ISO, CE and FDA marks for other well-respected organizations and their products, and establishing significant Environment Management (EMS) and Occupational Health and Safety Management (OHSMS) systems in the process.

Third Party Negotiations

Negotiations with AEMEA for a significant investment into DMI were terminated by the Board in the second quarter of 2010; both parties being unable to reach a suitable agreement.

Neil White: "After protracted discussions, in light of recent developments at DMI and with the closer realization as to the growth potential of X-Halo we firmly believe that it was in the best interests of our investors not to pursue this particular line of enquiry at this stage."

Jas Gill concurs: "DMI's hand grows stronger by the day... the timing and terms originally on offer no longer reflected our current position. Nor were the investors prepared to compromise on this new realisation."

Despite this DMI remains open to all reasonable offers made: *"Protecting the vested interests of our shareholders and the autonomous nature of DMI's operations as they are today, is paramount. Selling short on what is already an excellent long-term proposition is simply not an option."*

ABOUT DELMEDICA INVESTMENTS

Based in Singapore, Delmedica Investments are a specialist funding company offering investors access to the immense potential of the global biotechnology industry. Via their impressive resources and network of health care professionals, Delmedica identify new opportunities with tangible commercial potential, opportunities that represent low risk, high-growth and clear exit strategies. Recently the healthcare industry replaced technology as the fastest growing sector in the U.S., now accounting for 12% of the total U.S. economy. Find out how Delmedica offers the investor access to innovations that represent the future of the health care industry.

TO ORDER YOUR X-halo VISIT

www.x-halo.com

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