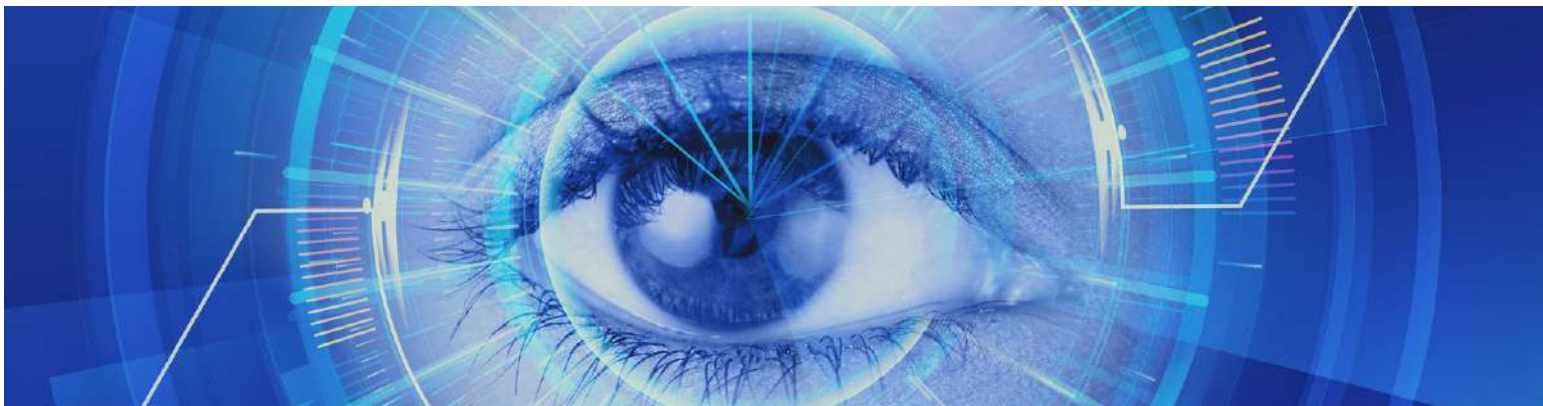


## RESEARCH & INNOVATION ARE OUR DRIVING FORCE!



### EDITO

#### Welcome to the latest edition of NOVAX Newsletter!

As we step into 2024, the landscape of medical device regulations in the field of ophthalmology continues to evolve, presenting both challenges and opportunities for industry players.

For many months, our Regulatory Team has been working non-stop on getting MDR approval.

The world of ophthalmic devices is keeping us on our toes, with regulatory changes, innovations, new exclusive licenses granted to NOVAX to enhance patient experience.

We are delighted to have you in our family as distributor, and we strive to provide you with quality and dedicated services.

Novax is looking for your success and helping you expanding your business in 2024.

**Victor Dias Ferreira**  
CEO

### NEWS

#### MDR REGULATIONS

Staying compliant with ever-evolving regulations is crucial to ensuring the safety and efficacy of these innovations.

As you know, the EU MDR entered into application on 26 May 2021. An extension was granted to medical devices companies to allow them to be in alignment with the new regulations through Regulations 2023/607.

Notified bodies were struggling to process the applications for re-certification in time, meaning that there was a risk of acute shortages of supplies. Regulations (EU) 2021/745 and (EU) 2017/746 were then amended as regards to the transitional provisions for certain medical devices.

NOVAX has been working on updating its declarations and CE marking allowing our products (called “legacy devices” under MDR) to be placed on the market after the date of application of the corresponding regulation (26 May 2021 amended to 27 May 2024), until the sooner of expiry of certificate or end of 2028 (December 31st).

In parallel, NOVAX has been also working on the MDR requirements for all of its products and updating its technical dossiers as changes will need to be implemented such as new symbols, additional information and clarification related to UDI, data, layout, change of class for some medical devices.

Do not hesitate to contact us should you have questions about MDR.

Also, more information can be found under: <https://eumdr.com>

## GETTING TO KNOW OUR TEAM

### Portrait of the quarter:

#### *Natacha Dias Ferreira, Sales Director*

From 2008-11 and again since 2014, Natacha has been working with the family business. As you may know, Natacha is one of Victor's daughters. She was born in France, lived in Rome, and then moved in the South of France.

Natacha holds a bachelor degree in corporate communication from SKEMA (Sophia Nice Antipolis, France & Hawai'i Pacific University (USA)). Before joining NOVAX, she worked in the hospitality business for major US companies.

In 2014, with her expertise, she started working in the Sales & Logistics department and, in 2022, she was promoted as Sales Director.

Along the years, she has been implementing strategic sales initiatives and fostering distributor relationships.

Thanks to her solution-oriented skills, she has been helping NOVAX & VITEVAX build and maintain strong client relationships and ensuring customer satisfaction.

In her spare-time, Natacha loves cooking, having friends and family over, as well traveling with her husband & daughter (3 year-old) around the globe.



## SALES & MARKETING UPDATES - MERCHANDISING

You were many to ask NOVAX to provide you with NOVAX / VITEVAX merchandising products, and we listened!

Soon, we will introduce you with a catalogue to choose from.

Happy shopping!

## SURVEYS

Dear Distributors, your opinion matters to us!

In the next few weeks, you might receive some surveys.

These surveys are essential to Novax as they allow us to meet and anticipate your needs.

Please do not hesitate to call us, email us should you have any questions, enquiries, we are here to assist you.

## 2024 ANNUAL AUDITS

Novax is happy to inform you that on February 2024, it has passed successfully our MDD audit.

Next step will be the MDR audit.

### TRANSITION TIMELINES FROM THE DIRECTIVES TO THE MEDICAL DEVICES REGULATION



NOVAX<sup>®</sup>  
PHARMA

VITEVAX<sup>®</sup>  
PHARMA

Your feedback  
is important to us.

Please contact us  
for any enquiry at:  
[info@novaxpharma.com](mailto:info@novaxpharma.com)