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## **NOVALIQ RECEIVES EU QUALITY MANAGEMENT CERTIFICATE ACCORDING TO NEW MEDICAL DEVICE REGULATION (MDR)**

HEIDELBERG, Germany, October 12, 2021 – Novaliq, a biopharmaceutical company focusing on first- and best-in-class ocular therapeutics based on the unique EyeSol® water-free technology, today announced that it has implemented and applies a quality management system in accordance with Annex IX, Chapter I of the EU Medical Device Regulation (MDR), for conformity assessment of its medical devices NovaTears®, NovaTears®+Omega-3 and EvoTears™ OMEGA.

Medical devices are products or equipment intended generally for a medical use. On 26 May, 2021, the Medical Device Directive (MDD) has been replaced by the new Medical Device Regulation (MDR). MDR is designed to be an improved version of MDD, increasing in particular the standards on quality and safety measures.

Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet legal requirements to ensure they are safe and perform as intended. Manufacturers can place a CE (Conformité Européenne) mark on a medical device once it has passed a conformity assessment.

The changes introduced in the MDR affect a variety of aspects in the CE marking process. Some of these processes include device classification, technical file documentation, new responsibilities for the European Medicines Agency (EMA) and post-market activities. The goal of this is to increase the qualitative standards of medical devices within the EU, ensuring improved levels of safety whilst encouraging innovation.

An audit by mdc medical device certification GmbH has proven that Novaliq's quality management system fulfils the respective requirements and a conformity certificate has been issued in September 2021.

“We are very pleased with our decision to implement MDR already in 2021. The safety and quality of our products is a priority to us. Therefore we always seek to implement the highest standards for the benefit of patients, customers and partners ,” said Christian Roesky, Ph.D., Managing Director and CEO, Novaliq.

### **About Novaliq's medical device eye care products**

NovaTears® is the first water-free and preservation-free eye drop for the treatment of dry eye. The product is CE certified since 2014 and successfully commercialized in Australia/New Zealand by AFT Pharmaceuticals and in Europe as EvoTears™ by Ursapharm. As the first-of-its kind, NovaTears® offers a new mode of action by acting as a lubricating lipid layer stabilizer and evaporative barrier for improving tear film stability and quality. NovaTears® is clinically validated by demonstrating improvement in signs and symptoms in evaporative dry eye disease (DED) and dry eye associated with meibomian gland

dysfunction (MGD) patients.<sup>1,2</sup> With millions of NovaTears®/EvoTears™ units sold, the technology is proven to be safe and well accepted.

NovaTears®+Omega-3 is the first vegan eye drop formulation combining perfluorohexyloctane, the sole ingredient of NovaTears®, with omega-3 fatty acid esters which are a natural component of the tear film and potentially important for evaporation and oxidative stress resistance. The product is free of antimicrobial preservatives and does not contain phosphate. NovaTears®+Omega-3 eye drops provide an easy and unique way to supply omega-3 right to the place of application for patients concerned about their eyes. The product received CE-marking in October 2017 and is commercialized in Australia/New Zealand by AFT Pharmaceuticals and in Europe as EvoTears™ OMEGA by Ursapharm.

### **About Novaliq**

Novaliq is a biopharmaceutical company focusing on the development and commercialization of first- and best-in-class ocular therapeutics based on EyeSol®, the worldwide first water-free technology. Novaliq offers an industry-leading portfolio addressing today's unmet medical needs of millions of patients with eye diseases. Novaliq GmbH is headquartered in Heidelberg, Germany and Novaliq Inc. has an office in Cambridge, MA, USA. The long-term shareholder is dievini Hopp BioTech holding GmbH & Co. KG, an active investor in Life and Health Sciences companies. More on [www.novaliq.com](http://www.novaliq.com).

### **References**

1. Steven P, Scherer D, Krösner S, et al. Semifluorinated Alkane Eye Drops for Treatment of Dry Eye Disease--A Prospective, Multicenter Noninterventional Study. *J Ocul Pharmacol Ther.* 2015;31(8):498-503.
2. Steven P, Augustin AJ, Geerling G, et al. Semifluorinated Alkane Eye Drops for Treatment of Dry Eye Disease Due to Meibomian Gland Disease. *J Ocul Pharmacol Ther.* 2017;33(9):678-685.

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