

Wöhlk Contactlinsen receives MDR certificate

Schönkirchen, November 06, 2024: It's done and a real milestone in the 77-year history of the northern German contact lens manufacturer: Wöhlk Contactlinsen GmbH has received the MDR certificate. The European Medical Device Regulation (MDR; Regulation 2017/745) has been in force since May 2021, replacing the two previous European medical device directives MDD and AIMDD. The certification was a real feat of strength for the medium-sized company: The MDR requires a full recertification of all existing products (legacy products), some of which have been on the market for years, to ensure that they meet the increased regulatory requirements of this new regulation. Wöhlk therefore also had to recertify those contact lenses that have been helping wearers to see better for years - or even decades - without any complaints.

“The certification process was preceded by a fundamental analysis: Which products could be included in the MDR? Which contact lenses did Wöhlk have to consolidate with a heavy heart for business reasons, even if they were niche products such as the colored Sport Contrast, which did not exist on the market in this form a second time?” explains Dirk Reschat, Head of Quality Management and Regulatory Affairs at Wöhlk Contactlinsen. “The effort involved in obtaining this certificate was enormous: we had to expand and train our QM department, use external services such as toxicological tests in laboratories and meet various technical and administrative requirements. This can only be achieved with a good strategy and an excellent team”.

Originally, all requirements should have been met by May 26, 2024. As of June 2024, 26,185 certificates had been applied for under the MDR - at that time, only 8,905 certificates had been issued. In reality, this would have meant that a large proportion of medical devices would have disappeared from the European market*. Another law then made it possible to extend the MDD certificates that had expired in May 2024 with a so-called “Confirmation Letter” for regulatory purposes. “Even if we could have kept our products on the market until December 31, 2028 in this

way, we are incredibly happy to now have our MDR certificate in our hands,” says Dirk Reschat.

The certification has one major advantage: the contact lens manufacturer from Schönkirchen can now approve new products on the market again. “This is particularly important for our company, which has its own material production, research and development facilities,” explains Hiroko Aikawa, Managing Director of Wöhlk Contactlinsen. “We are proud and happy to be one of the first companies in our industry to receive this certificate. Our strength has always been to respond to customer wishes. Our aim is to once again present new and further developments of individual contact lenses on the market. Our customers can now look forward to new products from Wöhlk in the near future.”

* Source: Bundesverband Medizintechnologie e.V.

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About Wöhlk Contactlinsen GmbH

With the invention of the contact lens over 75 years ago, Heinrich Wöhlk not only established modern contact optics, but also laid the foundation for Wöhlk Contactlinsen GmbH. Today, our company is a pioneer in the development of innovative materials, manufacturing processes and products. Research, development and production take place in Schönkirchen near Kiel, the company headquarters with its research laboratory, development department and contact lens studio. Under the leadership of Managing Director Hiroko Aikawa, a total of around 130 highly qualified and specialized specialists work here on a common vision: superior contact lenses for the best possible visual quality and maximum wearing comfort.

Since 2020, Wöhlk Contactlinsen GmbH has been a subsidiary of the Japanese contact lens manufacturer SEED Co, Ltd. This cooperation ensures a strong position on the international market and also enables a comprehensive product portfolio: While Wöhlk is an expert in individual contact lenses, SEED Contact Lens focuses on the production of daily lenses.

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