Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021

Registration No.: SX 1566826-1

Certificate Holder: Wöhlk Contactlinsen GmbH

Bürgermeister-Schade-Str. 12-16

24232 Schönkirchen

Germany

Scope: Design and development, manufacture and distribution of

contact lenses and services related to the fitting. Manufacture and distribution of contact lens materials.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

 Report No.:
 1151697-10

 Effective date:
 2024-08-21

 Expiry date:
 2025-06-16

 Issue date:
 2024-08-21

Replaces certificate SX 1566826-1 issued 2023-07-27

Dipl.-Ing. Anja Fechner TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

Anja techni

This certificate can be validated on https://www.certipedia.com





Certificate

Quality Management System

EN ISO 13485:2016

Germany

EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021

Registration No.: SX 1566826-1

Certificate Holder: Wöhlk Contactlinsen GmbH

Bürgermeister-Schade-Str. 12-16

24232 Schönkirchen

Germany

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Wöhlk Contactlinsen GmbH Bürgermeister-Schade-Str. 12-16 24232 Schönkirchen Germany	Design and development, manufacture and distribution of contact lenses and services related to the fitting. Manufacture and distribution of contact lens materials.
/02	c/o Wöhlk Contactlinsen GmbH Professor-Küntscher-Str. 2 24232 Schönkirchen	Storage and shipping

This certificate can be validated on https://www.certipedia.com



