

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX

SX 1566826-1

Organization:

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.: 1115577-20 Effective date: 2023-07-27 Expiry date: 2025-06-16 Issue date: 2023-07-27

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Dipl.-Ing. (FH) Martin Wolf TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

TÜVRheinland

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Bürgermeister-Schade-Str. 12-16

24232 Schönkirchen

Germany

The scope of certification also covers the following:

| 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 Germany | Storage and shipping |
| /03 | c/o Wöhlk Contactlinsen GmbH Söhren 44 24232 Schönkirchen Germany | Storage |

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