



EG – KONFORMITÄTSERKLÄRUNG

EC DECLARATION OF CONFORMITY · DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ · ЕС – СЕРТИФИКАТ СООТВЕТСТВИЯ

Name und Adresse des Herstellers: / **Wöhlk Contactlinsen GmbH**
Name and address of the manufacturer: / **Bürgermeister-Schade-Str. 12 - 16**
Nom et adresse du fabricant: / **24232 Schönkirchen**
Nome e indirizzo del fabbricante: / **Germany**
Название и адрес производителя:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che /
мы заявляем о полной ответственности, что

das hergestellte Medizinprodukt: /
the manufactured medical device: /
le produit de dispositif médical: /
el producto de dispositivo medico: /
то произведённый медицинский продукт:

CONTACT individual BIO
CONTACT individual BIO TDS
CONTACT individual BIO TD
CONTACT individual BIO TP

CONTACT individual BIO UV
CONTACT individual BIO UV TDS
CONTACT individual BIO UV TD
CONTACT individual BIO UV TP

CONTACT individual multi BIO
CONTACT individual multi BIO TDS
CONTACT individual multi BIO TD
CONTACT individual multi BIO TP

CONTACT individual multi BIO UV
CONTACT individual multi BIO UV TDS
CONTACT individual multi BIO UV TD
CONTACT individual multi BIO UV TP

CONTACT individual multi FEN BIO
CONTACT individual multi FEN BIO TP

CONTACT individual multi FEN BIO UV
CONTACT individual multi FEN BIO UV TP

EGO_soft BIO
EGO_soft BIO TDS
EGO_soft BIO TD
EGO_soft BIO TP

EGO_soft BIO UV
EGO_soft BIO UV TDS
EGO_soft BIO UV TD
EGO_soft BIO UV TP

EGO_soft multi BIO
EGO_soft multi BIO TDS
EGO_soft multi BIO TD
EGO_soft multi BIO TP



wöhlk
CONTACTLINSEN

EGO_soft multi BIO UV
EGO_soft multi BIO UV TDS
EGO_soft multi BIO UV TD
EGO_soft multi BIO UV TP

EGO_soft multi FEN BIO
EGO_soft multi FEN BIO TP

EGO_soft multi FEN BIO UV
EGO_soft multi FEN BIO UV TP

Basis UDI-DI: / Basic-UDI-DI: /
Base UDI-DI / Base UDI-DI: / Основание UDI-DI **4044497 012 55**

Single Registration Number (SRN) **DE-MF-000022424**

der Klasse: / of class: /
de la classe: / di classe: / класса: **II a**

Zweckbestimmung; / Intended purpose: / Objectif
visé: / Scopo previsto: / Предназначение: **Reusable soft contact lenses for correction of
vision defects (myopia, hyperopia, astigmatism,
presbyopia) for daily wear in healthy eyes**

nach Anhang VIII der (EU) 2017/745 / according to Annex VIII to (EU) 2017/745 / selon l'annexe VIII de la (EU)
2017/745 / secondo l'allegato VIII della (EU) 2017/745/ по дополнению VIII Закона (EU) 2017/745

(EU) 2017/745 entspricht. / Complies with all the General Safety and performance requirements of Annex I to the
Regulation (EU) 2017/745. / Conforme à toutes les exigences générales de sécurité et de performance de
l'annexe I du règlement (UE) 2017/745. / Conforme a tutti i requisiti generali di sicurezza e prestazioni
dell'Allegato I del Regolamento (UE) 2017/745. / Соответствует всем общим требованиям по безопасности и
рабочим характеристикам, приведенным в Приложении I к Регламенту (ЕС) 2017/745.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:
процедура оценки соответствия: **Anhang IX der (EU) 2017/745
Annex IX to (EU) 2017/745
Annexe IX de la (EU) 2017/745
Allegato IX di (UE) 2017/745
Приложение IX к (ЕС) 2017/745**

Zertifikat-Registrier-Nr.:/Certificate-Registration no:/
Certificat n°d'enregistrement:/Certificado Numero
di registrazione:/Сертификат Регистрационный
номер: **HZ 1566826-1**



Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato: /
Регистрационный орган:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany
CE 0197

Schönkirchen, 14.01.2026

Ort, Datum / Place, date / Lieu, date /
Luogo, data / Место, дата



Hiroko Aikawa / Managing Director