EG – KONFORMITÄTSERKLÄRUNG

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

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante: /
Название и адрес производителя:

Wöhlk Contactlinsen GmbH
Bürgermeister-Schade-Str. 12 - 16
24232 Schönkirchen
Germany

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 producit de dispositif médical: /
el producto de dispositivo medico: /
то произведённый медицинский продукт:

wöhlk AS
wöhlk AS RT
wöhlk AS BTK
wöhlk AS BT
wöhlk AS VPT

EGO_as
EGO_as RT
EGO_as BTK
EGO_as BT
EGO_as VPT

wöhlk BIFO AS
wöhlk BIFO AS RT
wöhlk BIFO AS BTK
wöhlk BIFO AS BT
wöhlk BIFO AS VPT

EGO_bifo as
EGO_bifo as RT
EGO_bifo as BTK
EGO_bifo as BT
EGO_bifo as VPT

wöhlk MULTI AS
wöhlk MULTI AS RT
wöhlk MULTI AS BTK
wöhlk MULTI AS BT
wöhlk MULTI AS VPT

EGO_multi as
EGO_multi as RT
EGO_multi as BTK
EGO_multi as BT

wöhlk
CONTACTLINSEN

EGO_multi as VPT

wöhlk MULTI FEN
wöhlk MULTI FEN RT
wöhlk MULTI FEN BT
wöhlk MULTI FEN VPT

EGO_multi FEN
EGO_multi FEN RT
EGO_multi FEN BT
EGO_multi FEN VPT

Diagnoselinse wöhlk AS
Diagnoselinse wöhlk AS RT
Diagnoselinse wöhlk AS BTK
Diagnoselinse wöhlk AS BT
Diagnoselinse wöhlk AS VPT

Diagnoselinse EGO_as
Diagnoselinse EGO_as RT
Diagnoselinse EGO_as BTK
Diagnoselinse EGO_as BT
Diagnoselinse EGO_as VPT

Diagnoselinse wöhlk BIFO AS
Diagnoselinse wöhlk BIFO AS RT
Diagnoselinse wöhlk BIFO AS BTK
Diagnoselinse wöhlk BIFO AS BT
Diagnoselinse wöhlk BIFO AS VPT

Diagnoselinse EGO_bifo as
Diagnoselinse EGO_bifo as RT
Diagnoselinse EGO_bifo as BTK
Diagnoselinse EGO_bifo as BT
Diagnoselinse EGO_bifo as VPT

Diagnoselinse wöhlk MULTI AS
Diagnoselinse wöhlk MULTI AS RT
Diagnoselinse wöhlk MULTI AS BTK
Diagnoselinse wöhlk MULTI AS BT
Diagnoselinse wöhlk MULTI AS VPT

Diagnoselinse EGO_multi as
Diagnoselinse EGO_multi as RT
Diagnoselinse EGO_multi as BTK
Diagnoselinse EGO_multi as BT

wöhlk
CONTACTLINSEN

Diagnoselinse EGO_multi as VPT

Diagnoselinse EGO_multi as
Diagnoselinse EGO_multi as RT
Diagnoselinse EGO_multi as BTK
Diagnoselinse EGO_multi as BT
Diagnoselinse EGO_multi as VPT

Diagnoselinse wöhlk MULTI FEN
Diagnoselinse wöhlk MULTI FEN RT
Diagnoselinse wöhlk MULTI FEN BT
Diagnoselinse wöhlk MULTI FEN VPT

Diagnoselinse EGO_multi FEN
Diagnoselinse EGO_multi FEN RT
Diagnoselinse EGO_multi FEN BT
Diagnoselinse EGO_multi FEN VPT

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

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE / по дополнению IX Закона 93/42/EEC

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll".
/meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.
/remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit.
/soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto. / соответствует требованиям законодательства медицинской продукции 93/42/EWG и их применении. заявление действительно в соответствии с принадлежащим к продукту Контрольному протоколу.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d'évaluation de la conformité: / Procedura di valutazione della conformità: процедура оценки соответствия:	**Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4 Directive 93/42/EEC Annex II, excluding Section 4 Directive 93/42/CEE Annexe II, hors section 4 Direttiva 93/42/CEE senza Allegato II, sezione 4 руководство 93/42/EWG Приложение 2, без подразделения 4**
Zertifikat-Registrier-Nr.:/ Certificate-Registration no:/ Certificat n°d'enregistrement:/ Certificado Numero di registrazione:/ Сертификáт Регистрациóнный нóмер:	**HD 1566826-1**
Gültig bis:/ Valid until:/ Valable jusqu'au:/ Valido fino al:/ действует до:	**2024/05/26**

Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:/ Регистрационный орган:	**TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany CE 0197**

Schönkirchen, 2023/08/01
Ort, Datum / Place, date / Lieu, date / Luogo, data / Место, дата

Dr. Dirk Lauscher / Managing Director