EG – KONFORMITÄTSERKLÄRUNG

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

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

Schönkirchen,2025/03/20
Ort, Datum / Place, date / Lieu, date / Luogo, data / Место, дата

Hiroko Aikawa / Managing Director