



Declaration of conformity
Konformitätserklärung
Déclaration de conformité
Dichiarazione di conformità
Deklaracja zgodności

Name of manufacturer: **Vistan Brillen GmbH**
Name des Herstellers: **Wilhelmstraße 16,**
Nom du producteur: **Schwäbisch Gmünd, 73525**
Nome del produttore: **Deutschland**
Nazwa producenta:

We declare under sole responsibility that the product
Wir erklären in alleiniger Verantwortung, daß das Produkt
Nous déclarons sous notre seule responsabilité, que le produit
Dichiariamo, sotto la nostra responsabilità
Oświadczamy, na własną odpowiedzialność, że dany produkt

Medical product **Class I ECRI Code (UMDNS) 11-667, GMDN Code 32816**
Medizinprodukt
Le dispositif médical
Il dispositivo medico
Produkt medyczny

UDI Code **currently not assigned**

Name of product: **Spectacle Frames (models see appendix)**
Produktname: **Korrektionsfassungen (Modelle siehe Anhang)**
Nom du produit: **Monture de Lunettes (appendix)**
Nome del prodotto: **Montatura da vista (appendix)**
Nazwa produktu: **Oprawy korekcyjne (dodatek)**

Complies with European standards EN ISO 12870, EN 16128 (if applicable)

conforms with the following regulations
den Bestimmungen der nachfolgenden Richtlinien entspricht
corresponds aux règlement de la
corrisponde ai regolamenti della
jest zgodny z następującymi rozporządzeniami

EU-Directive 93/42/EEC concerning medical devices
Richtlinie 93/42/EWG über Medizinprodukte
Directive du Conseil 93/42/CEE relative aux dispositifs médicaux
Direttiva 93/42/CEE concernente i dispositivi medici
Dyrektywa Rady 93/42/EWG r. dotycząca wyrobów medycznych

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Verordnung (EG) Nr. 1907/2006 zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH)
règlement (CE) n o 1907/2006 concernant l'enregistrement, l'évaluation et l'autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH)
regolamento (CE) n. 1907/2006 concernente la registrazione, la valutazione, l'autorizzazione e la restrizione delle sostanze chimiche (REACH)
Rozporządzenie (WE) nr 1907/2006 w sprawie rejestracji, oceny, udzielania zezwoleń i stosowanych ograniczeń w zakresie hemikaliów (REACH)

Schwäbisch Gmünd, 07.02.2020

Place and date of issue
Ort und Datum der Ausstellung
Lieu et date d'établissement
Luogo e data di emissione

Mr. Christian Seitz
President
Leitung
Directeur
Direttore

Ms. Monika Enssle
Safety Officer Frames
Sicherheitsbeauftragter Brillenfassungen
Chargé de Sécurité Montures
Direttore sicurezza Occhiali

Anhang/Appendix/Dodatek

Models:

| | | | |
|----------------|---------------|--------------|-------------|
| 515-4,5,6,8,9 | 2131-1,2,3, | 2364-1,2,3, | 2528-1,2, |
| 531-1,2, | 2133-1,2,3, | 2370-1,2,3, | 2530-1,2, |
| 577-1,2,3,4, | 2135-1,2,3, | 2374-1,2,3, | 2532-1,2, |
| 582-11,13, | 2137-1,2,3, | 2376-1,2,3, | 2534-1,2, |
| 583-1,2,3, | 2139-1,2,3, | 2378-1,2,3, | 2536-1,2, |
| 589-1,2,3,4, | 2141-1,2,3, | 2380-1,2,3, | 2538-1,2,3, |
| 654-1,6,8, | 2143-1,2,3, | 2382-1,2,3, | 2540-1,2,3, |
| 1009-1,2,3, | 2149-1,2,3, | 2384-1,2,3, | 2542-1,2,3, |
| 1135-11,12,13, | 2151-1,2,3,4, | 2386-1,2,3, | 2544-1,2,3, |
| 1190-1,2,3, | 2153-1,2,3, | 2390-1,2, | 2546-1,2,3, |
| 1241-1,3, | 2155-1,2,3, | 2392-1,2, | 2548-1,2,3, |
| 1243-1,3, | 2140-2, | 2394-1,2, | 2550-1,2,3, |
| 1381-1, | 2169-1,2,3, | 2396-1,2, | 2552-1,2,3, |
| 1383-1, | 2171-1,2,3, | 2398-1,2, | 2554-1,2,3, |
| 1416-1, | 2173-1,2,3, | 2400-1,2, | 2556-1,2,3, |
| 1418-1, | 2175-1,2,3, | 2402-1,2, | 2558-1,2,3, |
| 1679-1,2, | 2177-1,2,3, | 2404-1,2, | 2560-1,2,3, |
| 1697-1,2,3, | 2179-1,2,3, | 2406-1,2, | 4073-1,3, |
| 1817-1,2,3, | 2181-1,2,3, | 2410-1,2, | 4295-1,2,3, |
| 1861-1,2,3, | 2182-1,2,3, | 2412-1,2, | 4323-1,2,3, |
| 1891-1, | 2183-1,2,3, | 2414-1,2, | 4337-1,2,3, |
| 1893-1, | 2185-1,2,3, | 2416-1,2, | 4400-1,2,3, |
| 1924-1, | 2187-1,2,3, | 2418-1,2, | 4401-1,2,3, |
| 1927-1, | 2189-1,2,3, | 2420-1,2, | 4404-1,2,3, |
| 1965-1, | 2191-1,2,3, | 2422-1,2, | 4408-1,3, |
| 1967-1,2,3, | 2193-1,2,3, | 2424-1,2, | 4410-1,2,3, |
| 1969-1,2,3, | 2195-1,2,3, | 2426-1,2, | 4412-1,2,3, |
| 1981-1,2,3, | 2212-2, | 2428-1,2, | 4413-1,2,3, |
| 1985-1,2,3, | 2214-1,2, | 2430-1,2, | 4414-1,2,3, |
| 1989-1,2,3, | 2252-1,2,3, | 2442-1,2,3, | 4415-1, |
| 2003-1,2,3, | 2256-1,2, | 2444-1,2,3, | 4416-1,2,3, |
| 2005-1,2,3, | 2258-1,2, | 2446-1,2,3, | 4418-1,2,3, |
| 2007-1,2,3, | 2260-1, | 2448-1,2,3, | 4420-1,2,3, |
| 2009-1,2,3, | 2262-1,2, | 2450-1,2,3, | 4421-1,2,3, |
| 2013-1,2,3, | 2264-1,2, | 2452-1,2,3, | 4422-1,2, |
| 2017-1,2,3, | 2266,-1,2, | 2454-1,2,3, | 4424-1,2,3, |
| 2019-1,2,3, | 2270-1,3, | 2456-1,2,3, | 4428-1,2,3, |
| 2021-1,2,3, | 2276-1,2,3, | 2458-1,2,3, | 4428-1,2,3, |
| 2025-1,2,3, | 2278-1,2, | 2465-1,2, | 4431-1,2,3, |
| 2027-1,2,3, | 2280-1,2, | 2466-1,2, | 4432-1,2,3, |
| 2029-1,2,3, | 2282-1,2, | 2467-1,2, | 4434-1,2,3, |
| 2039-1,2,3, | 2286-1,2,3, | 2468-1,2, | 4435-1,2,3, |
| 2041-1,2,3, | 2288-1,2,3, | 2470-1,2, | 4437-1,2,3, |
| 2043-1,2,3, | 2290-1,2,3, | 2472-1,2, | 4438-1,2,3, |
| 2045-1,2,3, | 2292-1,2,3, | 2474-1,2, | 4439-1,2,3, |
| 2047-1,2,3, | 2296-1,2,3, | 2476-1,2, | 4440-1,2,3, |
| 2049-1,2,3, | 2310-1,2, | 2478-1,2, | 4441-1,2,3, |
| 2051-1,2,3, | 2312-1,2, | 2480-1,2, | 4442-1,2,3, |
| 2053-1,2,3, | 2314-1,2, | 2482-1,2, | 4443-1,2,3, |
| 2055-1,2,3, | 2316-1,2, | 2484-1,2, | 4444-1,2,3, |
| 2057-1,2,3, | 2318-1,2, | 2486-1,2, | 4445-1,2,3, |
| 2059-1,2,3, | 2320,-1,2, | 2488-1,-2,3, | 4446-1,2,3, |
| 2061-1,2,3, | 2322,-1,2, | 2490-1,2,3, | 4447-1,2,3, |
| 2063-1,2,3, | 2324-1,2, | 2492-1,2,3, | 4448-1,2,3, |
| 2085-1,2,3, | 2326-1,2, | 2494-1,2,3, | 4449-1,2,3, |
| 2087-1,2,3, | 2330-1,2,3, | 2496-1,2,3, | 4450-1,2,3, |
| 2091-1,2,3, | 2332-1,2,3, | 2498-1,2,3, | 4451-1,2,3, |
| 2093-1,2,3, | 2334-1,2,3, | 2502-1,2,3, | 4452-1,2,3, |
| 2099-1,2,3, | 2338-1,2,3, | 2510-1,2, | 4453-1,2,3, |
| 2103-1,2,3, | 2340-1,2,3, | 2512-1,2, | 4454-1,2,3, |
| 2105-1,2,3, | 2344-1,2,3, | 2514-1,2, | 4455-1,2,3, |
| 2107-1,2,3, | 2348-1,2,3, | 2516-1,2, | 4456-1,2,3, |
| 2111-1,2,3, | 2352-1,2,3, | 2518-1,2, | 4457-1,2,3, |
| 2117-1,2,3, | 2354-1,2,3, | 2520-1,2, | 4458-1,2,3, |
| 2119-1,2,3, | 2358-1,2,3, | 2522-1,2, | 4459-1,2,3, |
| 2122-2, | 2360-1,2,3, | 2524-1,2, | 4460-1,2,3, |
| | 2362-1,2,3, | 2526-1,2, | 4461-1,2,3, |
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| 4478-1,2,3, | 6219-1,2,3, | 6532-1,2,3, | 11044-1,2,3, |
| 4479-1,2,3, | 6225-1,2,3, | 6534-1,2,3, | 11046-1,2,3, |
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| 4482-1,2,3, | 6239-1,2,3, | 6540-1,2, | 11052-1,2,3, |
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| 4484-1,2,3, | 6243-1,2,3, | 6544-1,2, | 11056-1,2,3, |
| 4485-1,2,3, | 6245-1,2,3, | 6546-1,2, | 11058-1,2,3, |
| 4487-1,2,3, | 6262-11,12,13,14, | 6548-1,2, | 11060-1,2,3, |
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| 4491-1,2,3, | 6269-1,2,3, | 6552-1,2, | 40051-1,2,3, |
| 4493-1,2,3, | 6271-1,2,3, | 6594-1,2, | 40052-1,2,3, |
| 4495-1,2, | 6273-1,2,3, | 6596-1,2, | 40053-1,2,3, |
| 4497-1,2,3 | 6279-1,2,3, | 6598-1,2,3, | 40054-1,2,3, |
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| 4531-1,2,3, | 6327-1,2,3 | 10045-1,2,3, | 41000-1,2,3, |
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| 5033-1,2,3, | 6408-2, | 10054-1,2,3, | 60053-1,2, |
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| 5039-1,2,3, | 6416-1,2,3, | 10055-1,2,3, | 60055-2, |
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| 5046-1,2 | 6426-1,2, | 11000-1,2,3, | 60067-1, |
| 5047-1,2 | 6428-1,2, | 11001-1,2,3, | 60068-1, |
| 5048-1,2 | 6430-1,2,3,4, | 11002-1,2,3, | 60069-1, |
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| 5050-1,2, | 6460-1,2,4,5,6, | 11005-1,2,3, | 60072-1,2,3, |
| 5051-1,2, | 6478-1,2, | 11010-1,2,3, | 60073-1,2,3, |
| 5052-1,2, | 6480-1,2, | 11012-1,2,3, | 60077-1, |
| 5053-1,2, | 6482-1,2, | 11014-1,2,3, | 60082-1,2,3, |
| 5055-1,2 | 6484-1,2, | 11016-1,2,3, | 60083-1,2,3, |
| 6009-1,2,3, | 6486-1,2, | 11018-1,2,3, | 60084-1,2,3, |
| 6015-11,12,13,14 | 6488-1,2, | 11020-1,2,3, | 60085-1,2,3, |
| 6047-1,2,3, | 6492-1,2,3, | 11022-1,2,3, | 60086-1,2,3, |
| 6053-12,12,14,15, | 6494-1,2,3, | 11024-1,2,3, | 60087-1,2,3, |

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69003-1,2,3,
69004-1,2,3.