

PRIVÉ REVAUX

EYEWEAR

EU Declaration of Conformity

Manufacturer: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Authorized EU representative: Safilo SpA

Via Settima Strada 15, 35129 Padova - Italy

Single Registration number (SRN): IT-AR-000028495

We Prive Goods, LLC., as manufacturer and under our sole responsibility herewith declare that the spectacle frame

Model: PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

Basic UDI-DI: 08188930211200QW

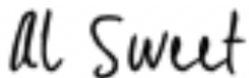
is a class I medical device (Annex VIII (EU) Regulation 2017/745, Chapter III Rule 1), whose intended use is the association, in the manufacture of eyeglasses, with ophthalmic lenses for the correction of visual defects.

Also declare that it is in conformity with the provisions of (EU) Regulation 2017/745 on Medical Devices and with the standard EN ISO 12870:2018

Miami, October 4, 2023

Signed for and on behalf of:

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(IT)

DICHIARAZIONE DI CONFORMITÀ UE

Fabbricante Prive Goods, LLC
1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801
PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Mandatario UE Safilo S.pA.
Via Settima Strada 15, 35129 Padova – Italy

Numero di registrazione unico (SRN): IT-AR-000028495

La sottoscritta Prive Goods, LLC. in qualità di fabbricante, sotto la propria esclusiva responsabilità dichiara che la montatura da vista di sua produzione

Modello: PRIVE REVAUX GOALS

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UDI-DI di base 08188930211200QW

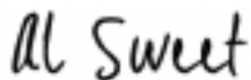
è un dispositivo medico di classe I (Regola 1 Capo III dell'allegato VIII del Regolamento (UE) 2017/745) il cui uso inteso è l'associazione, nella fabbricazione di occhiali da vista, a lenti oftalmiche per la correzione di difetti visivi.

Dichiara inoltre che essa è conforme al Regolamento (UE) 2017/745 relativo ai Dispositivi Medici e alla norma EN ISO 12870:2018

Miami, October 4, 2023

Firmato a nome e per conto di:

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(UK)

ДЕКЛАРАЦІЯ ВІДПОВІДНОСТІ СТАНДАРТАМ ЄС

виробник: Prive Goods, LLC
1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801
PO BOX 590368, Ft Lauderdale, Florida 33359 USA

уповноважений представник: Safilo SpA
Via Settima Strada 15, 35129 Padova - Italy

Унікальний номер реєстрації виробника: IT-AR-000028495

Нижче вказана компанія Prive Goods, LLC., у якості виробника під власну ексклюзивну відповідальність декларує, що оправа

МОДЕЛЬ PRIVE REVAUX GOALS

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Базовий код UDI-DI: **08188930211200QW**

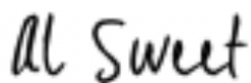
є медичним засобом I класу (Правило 1 Глави III додатку VIII Регламенту (ЄС) 2017/745), необхідним для виготовлення корекційних окулярів та має доповнятися лінзами для корекції дефектів зору.

Виробник також заявляє, що вироб відповідає вимогам Регламенту (ЄС) 2017/745, стосовно медичних засобів та норми EN ISO 12870:2018

Miami, October 4, 2023

Підписано від імені

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(BG)

ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ

производител: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

упълномощен представител: Safilo SpA

Via Settima Strada 15, 35129 Padova - Italy

Уникален регистрационен номер на производителя: IT-AR-000028495

Долуподписаната Prive Goods, LLC., като производител, на своя собствена отговорност декларира, че рамките за очила

МОДЕЛ PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

Основни UDI - DI: **08188930211200QW**

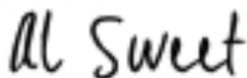
е медицинско изделие от клас I (Правило 1, Глава III от приложение VIII от Регламент (ЕС) 2017/745), чиято основна употреба е комбиниране с предписвани очни лещи за корекция на зрителни дефекти.

Декларира също, че е в съответствие с Регламент (ЕС) 2017/745 относно медицинските изделия и стандарт EN ISO 12870:2018

Miami, October 4, 2023

Подписана от името и за сметка на

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(CS) EU PROHLÁŠENÍ O SHODĚ

výrobce: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

zplnomocněným zástupcem: Safilo SpA

Via Settima Strada 15, 35129 Padova - Italy

Jedinečné registrační číslo výrobce: IT-AR-000028495

Níže podepsaná Prive Goods, LLC., jako výrobce, prohlašuje na svoji vlastní zodpovědnost, že brýlové obruba

MODEL **PRIVE REVAUX GOALS**

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Základní UDI-DI: **08188930211200QW**

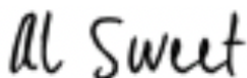
je zdravotnický prostředek třídy I (Pravidlo 1 Kapitola III Příloha VIII Nařízení (EU) 2017/745), jehož zamýšlené použití je sloučení s dioptrickými čočkami na korekci zrakových vad během výroby dioptrických brýlí.

Dále prohlašuje, že výrobek je v souladu s nařízením (EU) 2017/745 o zdravotnických prostředcích a s normou EN ISO 12870: 2018.

Miami, October 4, 2023

Podepsané za a jménemù

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(DA) EU OVERENSSTEMMELSESERKLÆRING

Fabrikant: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Bemyndiget repræsentant: Safilo SpA

Via Settima Strada 15, 35129 Padova - Italy

Fabrikantens individuelle registreringsnummer: IT-AR-000028495

Undertegnede Prive Goods, LLC., i sin egenskab som fabrikant, erklærer under eget ansvar, at brillestellet

MODEL PRIVE REVAUX GOALS

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Den grundlæggende UDI-DI: **08188930211200QW**

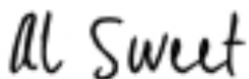
er et medicinsk udstyr i klasse I (Regel 1 Kapitel III i bilag VIII til Forordning (EU) 2017/745) hvis forudsete anvendelse er associationen med oftalmologiske linser til korrektion af synsfejl ved fremstilling af optiske briller.

Det erklæres desuden, at den er i overensstemmelse med forordning (EU) 2017/745 vedrørende Medicinske udstyr og med standard EN ISO 12870:2018

Miami, October 4, 2023

Underskrevet for og på vegne af

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(DE)
EU KONFORMITÄTSERKLÄRUNG

Hersteller: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Bevollmächtigter: Safilo SpA

Via Settima Strada 15, 35129 Padova - Italy

Einmalige Registrierungsnummer des Herstellers: IT-AR-000028495

Die Unterzeichnete Prive Goods, LLC, erklärt in ihrer Eigenschaft als Herstellerin und unter ausschließlich eigener Verantwortung, dass die Brillenfassung

MODELL: **PRIVE REVAUX GOALS**

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Basis-UDI-DI: **08188930211200QW**

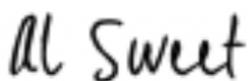
ein Medizinprodukt der Klasse I (Regel 1 Kapitel III Anhang VIII Verordnung (EU) 2017/745) ist, dessen beabsichtigter Zweck die Verbindung mit ophthalmischen Linsen bei der Herstellung einer Korrektionsbrille zur Korrektur von Sehfehlern ist.

Erklärt außerdem die Konformität des Modells mit der Verordnung (EU) 2017/745 über Medizinprodukte und der Norm EN ISO 12870:2018.

Miami, October 4, 2023

Gezeichnet im Namen und auf Rechnung der

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(EL)
ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

κατασκευαστής: Prive Goods, LLC
1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801
PO BOX 590368, Ft Lauderdale, Florida 33359 USA

εξουσιοδοτημένος αντιπρόσωπος: Safilo SpA
Via Settima Strada 15, 35129 Padova - Italy

Ενιαίος αριθμός καταχώρισης του κατασκευαστή: IT-AR-000028495

Η υπογεγραμμένη Prive Goods, LLC, υπό την ιδιότητα του κατασκευαστή, υπό ίδια και αποκλειστική ευθύνη δηλώνει ότι ο σκελετός οράσεως

ΜΟΝΤΕΛΟ: PRIVE REVAUX GOALS
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Βασικό UDI-DI: **08188930211200QW**

είναι ιατροτεχνολογικό προϊόν κατηγορίας I (Άρθρο 1 Κεφάλαιο III του παραρτήματος VIII του Κανονισμού (ΕΕ) 2017/745), η προβλεπόμενη χρήση του οποίου είναι η σύνδεσή του, κατά την κατασκευή γυαλιών οράσεως, με οφθαλμικούς φακούς για τη διόρθωση των οπτικών ατελειών.

Δηλώνει επίσης ότι συμμορφώνεται με τον κανονισμό (ΕΕ) 2017/745 σχετικά με τα Ιατροτεχνολογικά Προϊόντα και με το πρότυπο EN ISO 12870:2018

Miami, October 4, 2023

Υπογράφηκε εξ ονόματος και για λογαριασμό

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(ES) DECLARACIÓN UE DE CONFORMIDAD

Fabricante: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Representante autorizado: Safilo SpA

Via Settima Strada 15, 35129 Padova - Italy

Número de registro único del fabricante: IT-AR-000028495

La empresa abajo firmante, Prive Goods, LLC, declara en calidad de fabricante, bajo su propia y exclusiva responsabilidad, que la montura de gafas

MODELO **PRIVE REVAUX GOALS**

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UDI-DI básico: **08188930211200QW**


Es un producto sanitario de clase I (Regla 1, capítulo III del anexo VIII del Reglamento (UE) 2017/745), cuyo uso previsto es la asociación, en la fabricación de gafas graduadas, con lentes para la corrección de defectos visuales.

También declara que cumple con el Reglamento (UE) 2017/745 relativo a los productos sanitarios y con la norma EN ISO 12870:2018

Miami, October 4, 2023

Firmado en nombre y por cuenta de

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(ET)

ELI VASTAVUSDEKLARATSIOON

Tootja: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Volitatud esindaja: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Unikaalne tootja registreerimisnumber: IT-AR-000028495

Tootja Prive Goods, LLC, oma pädevuses tootjana ja vastutades ainuisikuliselt, et prilliraam

MUDEL PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

Põhi UDI-DI: **08188930211200QW**

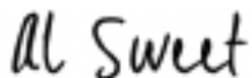
On I klassi meditsiiniseade Euroopa Parlamendi ja Nõukogu määruse 2017/745 VIII lisa kolmanda peatüki 1. reegli mõttes, mis on mõeldud kasutamiseks seoses prillide ja oftalmoloogiliste läätsede valmistamisega nägemise korrigeerimiseks.

Samuti deklareerib Ragione sociale, et see on vastavuses nii Euroopa Parlamendi ja Nõukogu määruses 2017/745 toodud sätetega meditsiiniseadmete kohta kui ka EN ISO 12870:2018 standardiga.

Miami, October 4, 2023

Allkirjastatud nimel

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(FI)

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

Valmistajall: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Valtuutetulla edustajalla: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Valmistajan rekisterinumero: IT-AR-000028495

Allekirjoittanut valmistajayritys Prive Goods, LLC, omalla yksinomaisella vastuullaan vakuuttaa, että silmälasinkehykset

MALLI **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Yksilöllinen UDI-DI-tunniste: **08188930211200QW**

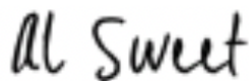
Ovat luokan I lääkinällinen laite (asetuksen (EU) 2017/745 liitteen VIII III luvun sääntö 1), jolle tarkoitettu käyttö on yhdistäminen näkövirheiden korjaamiseen määrättyihin oftalmisiin linsseihin silmälasien valmistamiseksi.

Valmistaja vakuuttaa lisäksi, että ne ovat lääkinällisiä laitteita koskevan asetuksen (EU) 2017/745 ja standardin EN ISO 12870:2018 mukaiset

Miami, October 4, 2023

Valmistajan puolesta allekirjoittanut

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(FR)
DÉCLARATION UE DE CONFORMITÉ

Fabricant: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Mandataire: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Numéro d'enregistrement unique du fabricant : IT-AR-000028495

La soussignée Privé Goods, LLC, en qualité de fabricant, déclare sous sa responsabilité exclusive que, la monture de lunettes

MODÈLE **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

IUD-ID de base : **08188930211200QW**

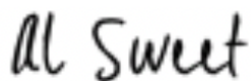
Est un dispositif médical de classe I (Règle 1, Chapitre III de l'annexe VIII du Règlement (UE) 2017/745) conçu pour être équipé, lors de la fabrication de lunettes de vue, de verres ophtalmiques pour la correction de défauts visuels.

Il déclare en outre que ce produit est conforme au Règlement (UE) 2017/745 relatif aux dispositifs médicaux et à la norme EN ISO 12870:2018

Miami, October 4, 2023

Signé au nom et pour le compte de

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(HR)
EU IZJAVA O SUKLADNOSTI

Proizvođač: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Ovlašteni zastupnik: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Jedinstveni registracijski broj proizvođača: IT-AR-000028495

Dolje potpisani Prive Goods, LLC, en u svojstvu proizvođača, pod isključivom odgovornošću izjavljuje da je su okviri za naočale

MODEL **PRIVE REVAUX GOALS**

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Osnovni UDI-DI: **08188930211200QW**

Medicinski proizvod I. klase (pravilo 1. poglavlje III. Priloga VIII. Uredbe (EU) 2017/745), čija je predviđena namjena upotreba s oftalmološkim lećama za korekciju poremećaja vida u proizvodnji naočala za vid.

Nadalje, izjavljuje da su sukladne s Uredbom (EU) 2017/745 u pogledu medicinskih proizvoda i normom EN ISO 12870:2018

Miami, October 4, 2023

Potpisano u ime i za račun

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(HU)
EU-MEGFELELŐSÉGI NYILATKOZAT

Gyártó: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Meghatalmazott képviselő: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

A gyártó egyedüli regisztrációs száma: IT-AR-000028495

Alulírott gyártó Prive Goods, LLC, saját és kizárólagos felelőssége tudatában kijelenti, hogy az optikai keret

MODELL: **PRIVE REVAUX GOALS**

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Alapvető eszközazonosító szám: **08188930211200QW**

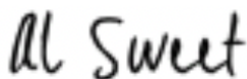
I. osztályba tartozó orvostechnikai eszköz (2017/745 (EU) Rendelkezés VIII. Melléklet III. fejezet 1. szabálya) amely célzott használata a látáshibákat javító dioptriás szemüvegekkel, kontaktlencsék közös használat.

Ezen kívül kijelenti, hogy megfelel az Orvostechnikai Eszközökre vonatkozó 2017/745 (EU) rendelkezésnek és az EN-ISO 12870:2018 szabványnak.

Miami, October 4, 2023

Aláírva alulírott nevében és megbízásából

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(LT) ES ATITIKTIES DEKLARACIJA

Gamintojas: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

įgaliotasis atstovas: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Unikalusis gamintojo registracijos numeris: IT-AR-000028495

Aš, žemiau pasirašęs (-iusi) Prive Goods, LLC, kaip gamintojas (-a) prisiimdamas (-a) visą atsakomybę, patvirtina, kad akinių rėmeliai

MODELIS **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Bazinis UDI-DI: **08188930211200QW**

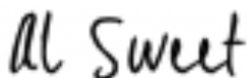
Yra medicinos priemonė priklausantys I klasei (kaip numato ES Reglamento 2017/745, VIII priedo, III skyriaus, 1 taisyklė) ir jų naudojimas siejamas su akinių rėmelių, į kuriuos tvirtinami oftalmologiniai lęšiai regėjimui pakoreguoti, gamyba.

Tuo pačiu patvirtina, kad gaminys atitinka ES Reglamento 2017/745 nuostatas dėl medicinos priemonių bei darnųjų standartą EN ISO 12870:2018.

Miami, October 4, 2023

Už ką ir kieno vardu pasirašyta

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(LV) ES ATBILSTĪBAS DEKLARĀCIJA

Ražotājs: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Pilnvarotais pārstāvis: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Ražotāja unikālais reģistrācijas numurs: IT-AR-000028495

Mēs, Prive Goods, LLC, kā ražotājs, un uz savu atbildību paziņojam, ka optiskais rāmis

MODELIS **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Pamata UDI-DI: **08188930211200QW**

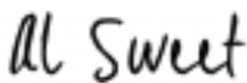
Ir I klases (Regulas (ES) 2017/745 VIII pielikuma 1. noteikuma III nodaļa) ir medicīnas ierīce kuru paredzētais lietojums ir briļļu ražošanā ar oftalmoloģiskām lēcām redzes defektu novēršanai.

Tas arī paziņo, ka tā atbilst Regulai (ES) 2017/745 par medicīnas ierīcēm un EN ISO 12870: 2018 standartam.

Miami, October 4, 2023

Parakstīts vārdā

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(ME) EU DEKLARACIJA O USAGLAŠENOSTI

Proizvođač: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Ovlašteni predstavnik: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Jedinstveni registracijski broj proizvođača: IT-AR-000028495

Firma Prive Goods, LLC, u svojstvu proizvođača i pod sopstvenom odgovornošću ovime daje izjavu da je okvir za naočare

Modela **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Osnovni UDI-DI: **08188930211200QW**

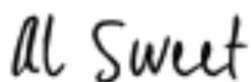
Predstavljaju medicinska sredstva razreda I (Pravilo 1 Odjeljak III priloga VIII Uredbe (EU) 2017/745) koji se prvenstveno koriste u kombinaciji sa dioptrijskim sočivima za korekciju vida prepisanim od strane lekara.

Također to izjavljuju su u skladu s Uredbom (EU) 2017/745 i zahtjevima koji su sadržani u standardu EN ISO 12870

Miami, October 4, 2023

Potpisano u ime i za račun

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(NL) EU CONFORMITEITSVERKLARING

Fabrikant: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Gemachtigde: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Uniek registratienummer van de fabrikant: IT-AR-000028495

De ondergetekende Prive Goods, LLC, in zijn hoedanigheid van fabrikant, verklaart op eigen verantwoording dat het brilmontuur.

MODEL PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

Basic UDI-DI: **08188930211200QW**

een medisch hulpmiddel is van klasse I (Regel 1, Hoofdstuk III van bijlage VIII van Verordening (EU) 2017/745), waarvan het beoogde gebruik, bij de vervaardiging van de bril, de combinatie is met lenzen voor het corrigeren van gebreken van het gezichtsvermogen.

Verklaart eveneens te voldoen aan Verordening (EU) 2017/745 betreffende medische hulpmiddelen en aan de norm EN ISO 12870:2018

Miami, October 4, 2023

Ondertekend namens en voor rekening van

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(NO) EU-SAMSVARERKLÆRING

Produsent: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Autorisert representant: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Produsentens unike registreringsnummer: IT-AR-000028495

Undertegnede Prive Goods, LLC, i egenskap av produsent, erklærer på eget ansvar, av brilleinnfatningen

MODELL PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

Grunnleggende UDI-DI: **08188930211200QW**


Er en medisinsk tilbehør i klasse I (Regel 1 Overskrift III i vedlegg VIII i EU-regulering 2017/745) hvis viktigste bruk er i forbindelse med reseptbelagte oftalmiske linser for å korrigere synsdefekter.

Den erklærer også at den er i samsvar med Eu-regulering 2017/745 om medisinsk utstyr og med EN ISO 12870: 2018-standarden.

Miami, October 4, 2023

Undertegnet for og på vegne av

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(PL)
DEKLARACJA ZGODNOŚCI UE

Producent: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Poważniony przedstawiciel: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Unikalny numer rejestracyjny producenta: IT-AR-000028495

Producent Prive Goods, LLC, oświadcza na własną odpowiedzialność, że oprawki do okularów korekcyjnych

MODEL: PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

UDI-DI Bazy: **08188930211200QW**

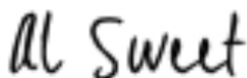
Są wyrobem medycznym Klasy I (Reguła 1 Rozdział III Załącznika VIII Rozporządzenia (UE) 2017/745), który przeznaczony jest do produkcji okularów do korekcji wad wzroku, w połączeniu z soczewkami optycznymi.

Producent deklaruje ponadto, że wyrób jest zgodny z Rozporządzeniem (UE) 2017/745 w sprawie wyrobów medycznych oraz z wymaganiami normy EN ISO 12870:2018.

Miami, October 4, 2023

Podpisano w imieniu i na rzecz

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(PT)
DECLARAÇÃO DE CONFORMIDADE UE

Fabricante: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Mandatário: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Número de registo único do fabricante: IT-AR-000028495

A abaixo assinada Prive Goods, LLC, na qualidade de fabricante, sob a sua exclusiva responsabilidade, declara que a armação de óculos

MODELO PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

UDI-DI básico: **08188930211200QW**

é um dispositivo médico de classe I (Regra 1 Capítulo III do anexo VIII do Regulamento (UE) 2017/745) cuja utilização prevista é a associação a lentes oftálmicas no fabrico de óculos de grau, para a correção de defeitos visuais.

Declara também que está em conformidade com o Regulamento (UE) 2017/745 relativo aos Equipamentos médicos e com a norma EN ISO 12870:2018

Miami, October 4, 2023

Assinado por e em nome de:

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(RO)

DECLARAȚIA DE CONFORMITATE UE

Producător: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Reprezentant autorizat: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Număr unic de înregistrare al producătorului: IT-AR-000028495

Subsemnata, Prive Goods, LLC, în calitate de producător, declară pe proprie răspundere că rama de ochelari de vedere

MODELUL **PRIVE REVAUX GOALS**

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UDI-DI de bază: **08188930211200QW**

Este un dispozitiv medical din clasa I (Regula 1 Capitolul III al Anexei VIII la Regulamentul (UE) 2017/745) destinat utilizării, în fabricarea a ochelarilor de vedere, împreună cu lentile oftalmologice pentru corectarea defectelor de vedere.

Declară, de asemenea, că rama respectă prevederile Regulamentului (UE) 2017/745 privind dispozitivele medicale și standardul SR ISO 12870:2018.

Miami, October 4, 2023

Semnat pentru și în numele

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(RU)

ДЕКЛАРАЦИЯ О СООТВЕТСТВИИ СТАНДАРТАМ ЕС

производитель: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Авторизованный представитель: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Уникальный номер регистрации производителя: IT-AR-000028495

Нижеуказанная компания Prive Goods, LLC, в качестве производителя под собственную эксклюзивную ответственность заявляет, что оправа

МОДЕЛЬ PRIVE REVAUX GOALS

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Базовый код UDI-DI: **08188930211200QW**


является медицинским приспособлением I класса (Правило 1 Глава III приложения VIII Регламента (ЕС) 2017/745), которое необходимо для производства коррекционных очков и дополняется линзами для коррекции дефектов зрения.

Производитель также заявляет, что изделие соответствует требованиям Регламента (ЕС) 2017/745, применимым к медицинским приспособлениям, и норме EN ISO 12870:2018

Miami, October 4, 2023

Подписано от имени

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(SK)
EÚ VYHLÁSENIE O ZHODE

Výrobca: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Splnomocnený zástupca: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Jedinečné registračné číslo výrobcu: IT-AR-000028495

Dolupodpísaná Prive Goods, LLC, ako výrobca, vyhlasuje na svoju vlastnú zodpovednosť, že okuliarové rám

MODEL **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Základné UDI-DI: **08188930211200QW**

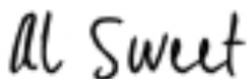
Je zdravotnícka pomôcka triedy I (Pravidlo 1 Kapitola III príloha VIII Nariadenia (EÚ) 2017/745), ktorej zamýšľané použitie je spojenie s dioptrickými šošovkami na korekciu zrakových chýb počas procesu výroby dioptrických okuliarov.

Tiež vyhlasuje, že výrobok je v súlade s nariadením (EÚ) 2017/745 o zdravotníckych pomôckach a s normou EN ISO 12870:2018.

Miami, October 4, 2023

Podpísané za a v mene

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(SL) IZJAVA EU O SKLADNOSTI

Proizvajalec: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Pooblaščen zastopnik: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Enotna registracijska številka proizvajalca: IT-AR-000028495

Spodaj podpisani(a) Prive Goods, LLC, kot proizvajalec, pod izključno lastno odgovornostjo izjavlja, da okvir za očala

MODEL **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Osnovni UDI-DI: **08188930211200QW**

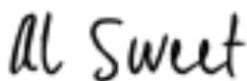
Je medicinski pripomoček razreda I (pravilo 1 v poglavju III Priloge VIII k Uredbi (EU) 2017/745), kjer je predvidena raba združitev, pri proizvodnji korekcijskih očal, z oftalmološkimi lečami za korekcijo napak vida.

Nadalje izjavlja, da je izdelek skladen z Uredbo (EU) 2017/745 o medicinskih pripomočkih in s standardom EN ISO 12870:2018.

Miami, October 4, 2023

Podpisano za in v imenu

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(SQ) DEKLARATË KONFORMITETI BE

Prodhuesi: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Përfaqësuesi i autorizuar: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Numri i regjistrimit unik i fabrikantit: IT-AR-000028495

Prive Goods, LLC, në cilësinë e tij si fabrikant, nën përgjegjësinë e vet ekskluzive, deklaron se korniza optike

MODEL **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

UDI-DI bazë: **08188930211200QW**

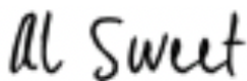
është një dispozitiv mjekësor i klasës I (Rregulli 1 Kapitulli III i aneksit VIII i Rregullores (BE) 2017/745) përdorimi i të cilit nënkupton shoqërimin, në fabrikimin syzeve për shikim, me lente oftalmike për korrigjimin e defekteve vizive.

Gjithashtu deklaron se është në përputhje me Rregulloren (BE) 2017/745 në lidhje me Dispozitivët Mjekësorë dhe me normën EN ISO 12870:2018

Miami, October 4, 2023

Nënshkruhet për llogari dhe në emër të

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(SR)

ЕЗ ДЕКЛАРАЦИЈА О УСАГЛАШЕНОСТИ

Производител: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Овластен претставник: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Јединствени регистрациони број произвођача: IT-AR-000028495

Prive Goods, LLC као произвођач, под искључивом одговорношћу изјављује да диоптријски оквири

МОДЕЛ: PRIVE REVAUX GOALS

UPC: 840219234342 840219234335 840219234359 840219234366

Основни UDI-DI: **08188930211200QW**


представљају медицинско средство I класе (правило 1, поглавље III прилога VIII Уредбе (ЕУ) 2017/745) намењено коришћењу уз диоптријска стакла која се уграђују у оквиру производње наочара за вид и која се издају уз рецепт ради корекције вида.

Поред тога, произвођач изјављује да су оквири усаглашени са Уредбом (ЕУ) 2017/745 којом се уређују медицинска средства, као и са стандардом EN ISO 12870:2018

Miami, October 4, 2023

Потписао у име и за рачун

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(SV)

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

Tillverkare: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Tillverkarens representant : Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Tillverkarens unika registreringsnummer: IT-AR-000028495

Undertecknad Prive Goods, LLC, i egenskap av tillverkaren, försäkrar under eget ansvar att glasögonbågen

MODELL **PRIVE REVAUX GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Grundläggande UDI-DI: **08188930211200QW**

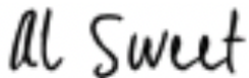
är en medicinsk enhet i klass I (regel 1 kapitel III i bilaga VIII till (EU) förordning 2017/745), vars avsedda användning gäller korrigerande av synfel vid tillverkning av slipade glasögon.

Företaget förklarar också att den uppfyller kraven i (EU) förordningen 2017/745 om medicintekniska samt standarden EN ISO 12870:2018

Miami, October 4, 2023

Undertecknat för

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning

PRIVÉ REVAUX

EYEWEAR

(TR)

AB UYGUNLUK BEYANI

üretici firma: Prive Goods, LLC

1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801

PO BOX 590368, Ft Lauderdale, Florida 33359 USA

Yetkili temsilcisi: Safilo SpA

Via Settima Strada 15, 35129 Padova – Italy

Üreticinin benzersiz kayıt numarası: IT-AR-000028495

Prive Goods, LLC, üretici vasfıyla ve kendi sorumluluğu altında olmak üzere,

MODELİ gözlük çerçevesinin **PRIVE REVAUX: GOALS**

UPC: 840219234342 840219234335 840219234359 840219234366

Temel UDI-DI: **08188930211200QW**

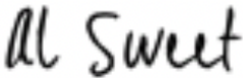
2017/745 sayılı AB Yönetmeliği Ek VIII dahilindeki Kural 1 Bölüm III doğrultusunda Sınıf I tıbbi cihaz olduğunu ve optik gözlük üretimindeki hedeflenen kullanım amacının, görme kusurlarını düzeltmek üzere optik gözlük camlarıyla beraber kullanılmak olduğunu beyan eder.

Ayrıca, EN ISO 12870:2018 normlarına ve Tıbbi Cihazlara ilişkin 2017/745 no.lu AB Yönetmeliği ile uyumlu olduğunu beyan eder.

Miami, October 4, 2023

Tarafından ve sıfatıyla imzalayan

Prive Goods, LLC.



Name: Al Sweet

Title: Director, Demand & Supply Chain Planning