

NAME DES HERSTELLERS FREUDENHAUS USA LLC  
4540 PGA BLV. STE 216  
PALM BEACH GARDENS, FLORIDA 33418, USA  
FDA REG NR. 3004787761 / OWNER OP. NR. 10032950

SRN : US-MF-000019641

NAME DES REPRESENTANTEN LOVEOPTIC GMBH  
RHEINSTRASSE 47  
D-65185 WIESBADEN

SRN: DE-AR-000019194

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt

PRODUKT NAMEFHONE EYEWEAR Sonnenbrillen / Acetate and/ or TITANIUM  
siehe Anhang Liste Produkte  
FH1-220101sun

BASIC UDI-DI 0795883frame-sunZ4

RISIKOKLASSE Klasse 1 , nicht steril, keine Messfunktion  
NOMENKLATUR EMDN code Q02100203, GMDN code 32816

KONFORMITAETSBEWERTUNGSVERFAHREN gemaess Artikel 52 (7) fuer Medizin produkte

Den Bestimmungen der nachfolgenden Richtlinien entspricht:

Verordnung (EU) No 2017/745 des European Parliament und des Rates of 5. April 2017 ueber Medizinprodukte  
Regulation (EU) No 2016/425 on Personal Protective Equipment Regulation and of the Council  
of 9. March 2016 on personal protective equipment

DIN EN ISO 12870

Wir unterhalten ein systematisches Verfahren zur Ueberwachung des Produktes nach dem Inverkehrbringen .

Verordnung (EC) No 1907/2006 zur Registrierung, Bewertung, Zulassung und Beschaerung chemischer Stoffe (REACH)

DIN EN ISO 10993


DIN EN 12472, DIN EN ISO 1811

Directive 94/62/EC

21 CFR 801.410 FDA reg. impact resistant lens ( drop ball test)

EN ISO 12312-1

Palm Beach Gardens, FL 01. June 2022

  
Sonja Ramdath  
Senior Quality Manager  
MDR Responsible Person  
FreudenHaus USA LLC

  
Stefan Flatscher  
Head of Design and Development  
FreudenHaus USA LLC

NAME OF MANUFACTURER FREUDENHAUS USA LLC  
4540 PGA BLV. STE 216  
PALM BEACH GARDENS, FLORIDA 33418, USA  
FDA REG NR. 3004787761 / OWNER OP. NR. 10032950

SRN : US-MF-000019641

NAME OF EU REPRESENTATIVE LOVEOPTIC GMBH  
RHEINSTRASSE 47  
D-65185 WIESBADEN  
SRN: DE-AR-000019194

We declare under sole responsibility that the medical product

PRODUCT NAME FHONE EYEWEAR  
SUNGLASSES / Acetate and/ or TITANIUM  
see appendix with list of product(s)  
FH1-220101SUN  
BASIC UDI-DI 0795883frame-sunZ4  
RISK CLASS Class 1 , non sterile, no measuring function  
NOMENCLATURE EMDN code Q02100203, GMDN code 32816  
CONFORMITY ASSESSMENT PROCEDURE pursuant to article 52 (7) for medical devices

Conforms with the following regulations :

Regulation (EU) No 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices

Regulation (EU) No 2016/425 on Personal Protective Equipment Regulation and of the Council of 9. March 2016 on personal protective equipment

DIN EN ISO 12870 Requirements and Testing for Spectacle frames.

We operate a systematic procedure after placing it in the market

Regulation (EC) No 1907/2006 on the Regulations, Evaluation, Authorization and Registration of Chemicals (REACH)

DIN EN ISO 10993 Bioconformity


DIN EN 12472, DIN EN ISO 1811 nickel permeability

Directive 94/62/EC on packaging and packaging waste

21 CFR 801.410 FDA reg. impact resistant lens ( drop ball test)

EN ISO 12312-1

Palm Beach Gardens, FL 01. June 2022

  
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Senior Quality Manager  
MDR Responsible Person  
FreudenHaus USA LLC

  
Stefan Flatscher  
Head of Design and Development  
FreudenHaus USA LLC

NOM DU PRODUCTEUR FREUDENHAUS USA LLC  
4540 PGA BLV. STE 216  
PALM BEACH GARDENS, FLORIDA 33418, USA  
FDA REG NR. 3004787761 / OWNER OP. NR. 10032950

SRN : US-MF-000019641

NOM DU REPRÉSENTANTS LOVEOPTIC GMBH  
RHEINSTRASSE 47  
D-65185 WIESBADEN  
SRN: DE-AR-000019194

Nous déclarons sous notre seule responsabilité, que le dispositif médical

NOM DU PRODUIT FHONE EYEWEAR  
des lunettes de soleil / Acetate and/ or TITANIUM  
voir annexe liste des produits  
FH1-220101sun

BASIC UDI-DI 0795883frame-sunZ4

CLASSE DE RISQUE Classe I - non sterile, sans fonction de mesure  
NOMENCLATURE EMDN code Q02100203, GMDN code 32816

PROCEDURE D'EVALUATION DE LA CONFORMITE conformément à l'article 52, (7) pour les dispositifs médicaux

corresponds aux reglements de la:

Reglement (UE) No 2017/745 du Parlement Europeen et du Conseil of 5. April 2017 relatif aux dispositifs médicaux  
Regulation (EU) No 2016/425 on Personal Protective Equipment Regulation and of the Council  
of 9. March 2016 on personal protective equipment

Conforme à la norme europeenne EN ISO 12870

Nous effectuons une procedure systematique pour contrôler le produit apres l'avoir mis sur le marche.

Reglement (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)

DIN EN ISO 10993

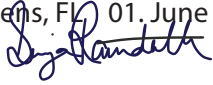
DIN EN 12472, DIN EN ISO 1811

Directive 94/62/EC

21 CFR 801.410 FDA reg. lentille résistante aux chocs ( drop ball test)

EN ISO 12312-1

Palm Beach Gardens, FL 01. June 2022

  
Sonja Ramdath  
Senior Quality Manager  
MDR Responsible Person  
FreudenHaus USA LLC



Stefan Flatscher

Head of Design and Development  
FreudenHaus USA LLC



Declaration of conformity  
Konformitätserklärung  
Déclaration de conformité  
Dichiarazione di conformità



FREUDENHAUS USA LLC

presents

**FH ONE**

NOME DEL PRODUTTORE FREUDENHAUS USA LLC  
4540 PGA BLV. STE 216  
PALM BEACH GARDENS, FLORIDA 33418, USA  
FDA REG NR. 3004787761 / OWNER OP. NR. 10032950

SRN : US-MF-000019641

NOME DEI RAPPRESENTANTI LOVEOPTIC GMBH  
RHEINSTRASSE 47  
D-65185 WIESBADEN  
SRN: DE-AR-000019194

Dichiariamo sotto la nostra esclusiva responsabilità che il dispositivo medico

NOME DEL PRODOTTO FHONE EYEWEAR  
occhiali da sole / Acetate and/ or TITANIUM  
vedere l'elenco dei prodotti in appendice  
FH1-220101SUN

BASIC UDI-DI 0795883frame-sunZ4

CLASSE DI RISCHIO Classe I - non sterile, sans fonction de mesure  
NOMENCLATURA EMDN code Q02100203, GMDN code 32816

PROCEDURA DI VALUTAZIONE secondo la sezione 52, (7) per i dispositivi medici  
DELLA CONFORMITÀ

Corrisponde al regolamento del :

Regolamento (UE) n. 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medici  
Regulation (EU) No 2016/425 on Personal Protective Equipment Regulation and of the Council  
of 9. March 2016 on personal protective equipment

Conforme alla norma europea EN ISO 12870

Eseguiamo una procedura sistematica per controllare il prodotto dopo averlo immesso sul mercato.

Regolamento (CE) n. 1907/2006 relativo alla registrazione, valutazione e autorizzazione delle sostanze chimiche,  
nonché le restrizioni applicabili a tali sostanze (REACH)

DIN EN ISO 10993

DIN EN 12472, DIN EN ISO 1811

Direttiva 94/62/EC

21 CFR 801.410 FDA reg. lente resistente agli urti ( drop ball test)

EN ISO 12312-1

Palm Beach Gardens, FL 01. June 2022

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FreudenHaus USA LLC

Stefan Flatscher

Head of Design and Development  
FreudenHaus USA LLC



Declaration of conformity  
Konformitätserklärung  
Déclaration de conformité  
Dichiarazione di conformità



Anhang / Annex / Vease / Annexe  
Basic UDI-DI

FH1-220101SUN  
0795883frame-sunZ4

6.1.2022

Marke/ Coll	Model / Description	GTIN / REF	Typ	Material Front	Material Temple
FHONE	BangBang DHV 381	0795853620597	Sunglasses	acetate	acetate
FHONE	BangBang HAV 391M	0795853620603	Sunglasses	acetate	acetate
FHONE	BangBang OCC 537	0795853620610	Sunglasses	acetate	acetate
FHONE	BangBang OLV 513	0795853620627	Sunglasses	acetate	acetate
FHONE	BangBang STEALTH	0795853620634	Sunglasses	acetate	acetate
FHONE	Boom ARC 590	0795853621020	Sunglasses	acetate	acetate
FHONE	Boom HAO 382	0795853621037	Sunglasses	acetate	acetate
FHONE	Boom STEALTH	0795853621044	Sunglasses	acetate	acetate
FHONE	Boom SVL 385	0795853621051	Sunglasses	acetate	acetate
FHONE	Boom TGH 109	0795853621068	Sunglasses	acetate	acetate
FHONE	Box (the) HGD	0795853625080	Sunglasses	titanium	titanium
FHONE	Box (the) LGN	0795853625073	Sunglasses	titanium	titanium
FHONE	Box (the) ONYX	0795853625066	Sunglasses	titanium	titanium
FHONE	Box (the) ROSE	0795853625097	Sunglasses	titanium	titanium
FHONE	Bristol BLK/GLD	0795853629576	Sunglasses	titanium	titanium
FHONE	Bristol CORAL	0795853629590	Sunglasses	titanium	titanium
FHONE	Bristol GLD	0795853629569	Sunglasses	titanium	titanium
FHONE	Bristol LGN	0795853629552	Sunglasses	titanium	titanium
FHONE	Bristol ROSE/GUN	0795853629583	Sunglasses	titanium	titanium
FHONE	DIVA BHN138 GLD	0795853629170	Sunglasses	acetate	titanium
FHONE	DIVA BUSC903 GUN	0795853629194	Sunglasses	acetate	titanium
FHONE	DIVA GRY125 DGR	0795853629187	Sunglasses	acetate	titanium
FHONE	DIVA IRIS860 LGN	0795853629200	Sunglasses	acetate	titanium
FHONE	DIVA SMOKE ROSE	0795853629217	Sunglasses	acetate	titanium
FHONE	Eastside BLK	0795853622409	Sunglasses	titanium	titanium
FHONE	Eastside BLU	0795853622423	Sunglasses	titanium	titanium
FHONE	Eastside GLD	0795853622447	Sunglasses	titanium	titanium
FHONE	Eastside LGN	0795853622461	Sunglasses	titanium	titanium
FHONE	Fairchild AQB SUN	0795853622805	Sunglasses	acetate	acetate
FHONE	Fairchild DHL SUN	0795853622829	Sunglasses	acetate	acetate
FHONE	Fairchild GTN SUN	0795853622843	Sunglasses	acetate	acetate
FHONE	Fairchild HAV4 SUN	0795853622867	Sunglasses	acetate	acetate
FHONE	Fairchild NIGHT SUN	0795853622881	Sunglasses	acetate	acetate
FHONE	FlatHammer 000 (crystal clear)	0795853622980	Sunglasses	acetate	acetate
FHONE	FlatHammer 303 (Braun/blau/grün)	0795853622997	Sunglasses	acetate	acetate
FHONE	FlatHammer 733 (lila/gelb/rot)	0795853623000	Sunglasses	acetate	acetate
FHONE	FlatHammer 100M (blk matte)	0795853623017	Sunglasses	acetate	acetate

FHONE	GIGI BKH 217	0795853623468	Sunglasses	acetate	titanium
FHONE	GIGI GSM 117	0795853623482	Sunglasses	acetate	titanium
FHONE	GIGI HAV 360	0795853623505	Sunglasses	acetate	titanium
FHONE	GIGI ONYX	0795853623529	Sunglasses	acetate	titanium
FHONE	Hunter CC 994	0795853624113	Sunglasses	acetate	acetate
FHONE	Hunter CRY	0795853624120	Sunglasses	acetate	acetate
FHONE	Hunter DBH 302M	0795853624137	Sunglasses	acetate	acetate
FHONE	Hunter GRY	0795853624144	Sunglasses	acetate	acetate
FHONE	Hunter ONYX	0795853624151	Sunglasses	acetate	acetate
FHONE	KitKat BLG 527	0795853624502	Sunglasses	acetate	acetate
FHONE	KitKat GKA 775	0795853624519	Sunglasses	acetate	acetate
FHONE	KitKat MILK 949	0795853624526	Sunglasses	acetate	acetate
FHONE	KitKat ONYX	0795853624533	Sunglasses	acetate	acetate
FHONE	KitKat TORT 350	0795853624540	Sunglasses	acetate	acetate
FHONE	Larchment M. NIGHT	0795853624663	Sunglasses	acetate	acetate
FHONE	Lille BLG 527	0795853624762	Sunglasses	acetate	acetate
FHONE	Lille ONYX	0795853624779	Sunglasses	acetate	acetate
FHONE	Lille SKY 525	0795853624786	Sunglasses	acetate	acetate
FHONE	Lille TGH 108	0795853624793	Sunglasses	acetate	acetate
FHONE	Lille TORT 330	0795853624809	Sunglasses	acetate	acetate
FHONE	OMO 397 ( s/w gefleckt)	0795853626025	Sunglasses	acetate	acetate
FHONE	OMO 409 H.SPA	0795853626032	Sunglasses	acetate	acetate
FHONE	OMO 569 RIV	0795853626049	Sunglasses	acetate	acetate
FHONE	OMO 585 (blue sky)	0795853626056	Sunglasses	acetate	acetate
FHONE	OMO 918 (rose crystal)	0795853626063	Sunglasses	acetate	acetate
FHONE	OMO HAV 375	0795853626018	Sunglasses	acetate	acetate
FHONE	OMO TGH 109	0795853626001	Sunglasses	acetate	acetate
FHONE	Paris 192 (s/w gefleckt)	0795853626124	Sunglasses	acetate	acetate
FHONE	Paris 232 (onyx Verlauf)	0795853626131	Sunglasses	acetate	acetate
FHONE	Paris 377 (havana / lila)	0795853626148	Sunglasses	acetate	acetate
FHONE	Paris 888 (rot/blau Verlauf)	0795853626155	Sunglasses	acetate	acetate
FHONE	Paris 994 CRY (vintage crystal?)	0795853626162	Sunglasses	acetate	acetate
FHONE	Rio BLA107/GUN	0795853629606	Sunglasses	acetate	titanium
FHONE	Rio BUSG903/LGN	0795853629637	Sunglasses	acetate	titanium
FHONE	Rio H2O 542/LGN	0795853629620	Sunglasses	acetate	titanium
FHONE	Rio SMOKE 110 / DGR	0795853629613	Sunglasses	acetate	titanium
FHONE	Rio TANG916/DGR	0795853629644	Sunglasses	acetate	titanium
FHONE	Rush BKH2	0795853626636	Sunglasses	acetate	acetate
FHONE	Rush BLY	0795853626643	Sunglasses	acetate	acetate
FHONE	Rush BRY	0795853626650	Sunglasses	acetate	acetate
FHONE	Rush GRY	0795853626667	Sunglasses	acetate	acetate
FHONE	Rush M. BLK	0795853626674	Sunglasses	acetate	acetate
FHONE	South BLK	0795853626902	Sunglasses	titanium	titanium
FHONE	South BLK-BLU	0795853626926	Sunglasses	titanium	titanium
FHONE	South by SW GLD/BLK	0795853629293	Sunglasses	titanium	titanium
FHONE	South by SW LGN	0795853629286	Sunglasses	titanium	titanium
FHONE	South by SW ROSE/GUN	0795853629279	Sunglasses	titanium	titanium
FHONE	South GLD-CRY	0795853626957	Sunglasses	titanium	titanium
FHONE	South GLD-HAV	0795853626964	Sunglasses	titanium	titanium
FHONE	South LGN-HAV	0795853626971	Sunglasses	titanium	titanium
FHONE	South LGN-PET	0795853626988	Sunglasses	titanium	titanium

FHONE	South ROSE	<b>0795853626995</b>	Sunglasses	titanium	titanium
FHONE	South ROSE-GRY	<b>0795853627008</b>	Sunglasses	titanium	titanium
FHONE	South V2 DGR	<b>0795853627848</b>	Sunglasses	titanium	titanium
FHONE	South V2 DGR-AZU	<b>0795853627800</b>	Sunglasses	titanium	titanium
FHONE	South V2 LGN	<b>0795853627831</b>	Sunglasses	titanium	titanium
FHONE	South V2 LGN_VL	<b>0795853627879</b>	Sunglasses	titanium	titanium
FHONE	South V2 LGN-SMOKE	<b>0795853627817</b>	Sunglasses	titanium	titanium
FHONE	South V2 ROSE	<b>0795853627824</b>	Sunglasses	titanium	titanium
FHONE	South V2 ROSE-GRY	<b>0795853627862</b>	Sunglasses	titanium	titanium
FHONE	South V3 Plus GLD/BLK PTH349	0795853629323	Sunglasses	titanium	titanium
FHONE	South V3 Plus LGN Gry 125	0795853629316	Sunglasses	titanium	titanium
FHONE	South V3 Plus ROSE/GUN Smoke	0795853629309	Sunglasses	titanium	titanium
FHONE	South West V3 LGN/ROSE Smoke	0795853629224	Sunglasses	titanium	titanium
FHONE	South West V3 DGR PINK890	0795853629255	Sunglasses	titanium	titanium
FHONE	South West V3 GLD/BLK gry125	0795853629231	Sunglasses	titanium	titanium
FHONE	South West V3 M.GLD TEAL575	0795853629262	Sunglasses	titanium	titanium
FHONE	South West V3 M.GUN TANG916	0795853629248	Sunglasses	titanium	titanium
FHONE	South-East DGR-BLK	<b>0795853627015</b>	Sunglasses	titanium	titanium
FHONE	South-East DGR-OPL	<b>0795853627022</b>	Sunglasses	titanium	titanium
FHONE	South-East GLD-CRY	<b>0795853627039</b>	Sunglasses	titanium	titanium
FHONE	South-East GLD-HAV	<b>0795853627046</b>	Sunglasses	titanium	titanium
FHONE	South-East ROSÉ	<b>0795853627053</b>	Sunglasses	titanium	titanium
FHONE	South-East ROSÉ-SPC	<b>0795853627060</b>	Sunglasses	titanium	titanium
FHONE	South-West BLK	<b>0795853627077</b>	Sunglasses	titanium	titanium
FHONE	South-West BLK-BLK	<b>0795853627084</b>	Sunglasses	titanium	titanium
FHONE	South-West GLD	<b>0795853627091</b>	Sunglasses	titanium	titanium
FHONE	South-West GLD-CRY	<b>0795853627107</b>	Sunglasses	titanium	titanium
FHONE	South-West LGN	<b>0795853627114</b>	Sunglasses	titanium	titanium
FHONE	South-West LGN-HAV	<b>0795853627121</b>	Sunglasses	titanium	titanium
FHONE	South-West LGN-SMOKE	<b>0795853627138</b>	Sunglasses	titanium	titanium
FHONE	The Aviator BLK	<b>0795853627190</b>	Sunglasses	titanium	titanium
FHONE	The Aviator BLK-BLK	<b>0795853627206</b>	Sunglasses	titanium	titanium
FHONE	The Aviator GLD	<b>0795853627213</b>	Sunglasses	titanium	titanium
FHONE	The Aviator GLD-CRY	<b>0795853627220</b>	Sunglasses	titanium	titanium
FHONE	The Aviator LGN	<b>0795853627237</b>	Sunglasses	titanium	titanium
FHONE	The Aviator LGN-BLU	<b>0795853627244</b>	Sunglasses	titanium	titanium