



DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER

Company Name: Chrome Hearts LLC
Address: 915 North Mansfield Avenue
Hollywood, CA 90038 USA
SRN (Single Registration Number): US-MF-000033929

AUTHORISED REPRESENTATIVE

Which is established in the European Union and has access to the Technical File.

EU Authorized Representative

Company Name: MedEnvoy Global BV
Full Address: Prinses Margrietplantsoen 33
Suite 123
2595 AM The Hague
The Netherlands
SRN (Single Registration Number): NL-AR-000023989
Notified Body (if applicable): Not Applicable

DESCRIPTION AND IDENTIFICATION


Brand: Chrome Hearts
Product Description: Spectacle Frames and Sunglasses
Basic UDI-DI: 0197249RX323U7
UDI-DI: Product reference list (see Annex I: RX and Annex I: SUN); all REFs identified with an "*" are also applicable to the Swiss market, all REFs identified with an "***" are also applicable to the UK market.
Classification: Spectacle frames are Class I, Rule I according to Annex VIII of the MDR 2017/745. Sunglasses are of Risk Category I PPE as per Annex I of the PPE Regulation.
Intended Use: The intended use of Spectacle frames is to hold corrective lenses to be worn on the face of individuals to correct refractive errors. The corrective lenses are not included.

COMPLIANCE

*This declaration of conformity is issued under the sole responsibility of Chrome Hearts. We hereby declare that the medical device(s) specified above meet the provision of the: **Medical Device Regulation (EU) 2017/745**. The Personal Protective Equipment specified above meet the provision of the: **Personal Protective Equipment Regulation (EU) 2016/745** and as per Annex IX section 8 Module C2.*

In conjunction with the following harmonised standards

EN-ISO 13485:2016 / EN-ISO 14971-2019 / EN-ISO 12870:2018
EN-ISO 12312-1:2013

Name: Kristy Ferguson
Function: Eyewear Operations
Signature/Date: 
Hollywood, CA 90038,
United States of America

10/2/24