



# US-Declaration of Conformity

**POMBERGER**  
Goisern

Manufacturer name: POMBERGER Goisern GmbH,  
Au 131, 4822 Bad Goisern  
Austria

Facility Registration Number: 3010370533

Owner/Operator Number: 10043416

## We declare under our sole responsibility that the following product

Product name: Frame, spectacle

Product Listing Number: D184298

Premarket Submission Type: 510(k) exempt

Product Code: HQZ

Activities: Manufacturer

Importers: GDI Optical, LLC  
6586 Hypoluxo Rd. Suite 105  
Lake Worth, Florida, 33467,  
UNITED STATES

## complies with the provisions of the following legislation:

Regulation (EU) 2017/745 of the European Parliament and of the Council concerning medical devices

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

US national standards ANSI Z80.5 (spectacle frames) and ANSI Z80.3 (sunglasses).

Bad Goisern, 2025-07-17

Place and date of issue

Jürgen Pomberger  
MDR Responsible Person  
Head of Business, CEO  
POMBERGER Goisern GmbH