



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 a.H., 17.08.2022

Place and date of issue

**POMBERGER**

GOISERN  
Hans Pomer Pomberger a.U.  
Au 131, 4822 Bad Goisern a.H.

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