



**ITALIAN  
CONCEPTS**

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**DECLARATION OF CONFORMITY**

**MEDICAL DEVICE REGULATION (EU) 2017/745**

According to ISO 12870-2016

**Italian Concepts S.A.**, with registered offices at 9 Adrianeiou Str. 115 25 Athens – Greece , VAT No. 997387993, registered at the Chamber of Commerce of Athens under the no. 129386701000 represented by Mrs. Anastasia Sarakatsanou Antonakou, CEO, in its capacity as the manufacturer, hereby declares, under its sole responsibility, that the spectacle frames

**DESCRIPTION OF THE PRODUCT: SPECTACLE FRAMES**

**BRAND NAME: GF FERRE**

**GCP: 52120419**

**EMDN: Q021002 , Q02100201, Q02100202**

**BASIC UDI-DI: 52120419EYEWEARFW**

**TYPE: ACETATE , STEEL**

**Standards Applied : EN ISO 13485:2016, EN ISO 10993-1:2009, EN ISO 12870:2018. ISO 12312-1:2013**

**Conformity Assessment:** According to Annex II+III of MDR (EU) 2017/745

are a class I medical device (rule 1 Chapter iii of Annex viii of (EU) Regulation 2017/745), which is intended for use in connection with, in the manufacturing of eyeglasses, ophthalmic lenses for correcting vision problems

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

Athens, 11/08/2023

**ITALIAN CONCEPTS S.A.**  
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