

## UE Declaration of Conformity

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**Manufacturers Name:** GIGISTUDIOS, SL

**Manufacturers Address:** C/ Bosc Tancat Nave 4, 08290 - Cerdanyola del Vallès (Barcelona, España)

**Notified Body name:** DOES NOT APPLY ACCORDING TO CONSIDERATION 60 OF MDR 2017/745

**Notified Body Address:** N/A

**Actor ID/SRN:** ES-MF-000025443

**Basic UDI-DI:** **84353399spectacleframesSH**

**Name of the Device (s):** SPECTACLE FRAMES

**Product description:** Spectacle frames & spectacle frames with tinted lenses for the purposes to be used with corrective lenses non-tinted or tinted under the brand Gigistudios

**Risk class:** Class I non sterile with no measurement function medical devices according to annex VIII, chapter III, Rule 1 of MDR 2017/745

**Notified Body name:** DOES NOT APPLY ACCORDING TO CONSIDERATION 60 OF MDR 2017/745

**Notified Body Address:** ----

**Notified Body Identification number:** ----

**Conformity assessment route:** GIGISTUDIOS, SL uses the following procedures for the CE-labeling of their products According to Annex II+III of MDR (EU) 2017/745:  
  
Class I: EC conformity declaration according to annex VIII

This declaration of conformity is issued under the sole responsibility of GIGISTUDIOS, SL. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signature: \_\_\_\_\_ Place and date (dd.mm.yyyy) of issue:

Cerdanyola del Vallès, 29/05/2023

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MARIA DEL MAR GINÉ  
TÉCNICO RESPONSABLE DE PRODUCTO