

UE Declaration of Conformity

Manufacturers Name: GIGISTUDIOS, SL

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

Authorized Representative Name (if applicable): LUÍS RAMO POMADA

Authorized Representative Address (if applicable): C/ Bosc Tancat Nave 4, 08290 - Cerdanyola del Vallès (Barcelona, España)

Basic UDI-DI: **84353399spectacleframesSH**

Name of the Device (s): SPECTACLE FRAMES

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

Classification: CLASS I

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 the Regulation MDR 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:

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MARIA DEL MAR GINÉ
TÉCNICO RESPONSABLE DE PRODUCTO

Cerdanyola del Vallès, 18/02/2022
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