

CONFORMITY DECLARATION

Roundten Europe SL, with registered office in C/ Mallorca 304 Principal 1, 08037 – Barcelona Spain, VAT Registration Number ESB66749490, registered at the Chamber of Commerce of Barcelona under the Tomo 45363, Folio 139 & Hoja B-485328 dated March 30th, 2016, duly represented by Ivan Ricart Gisbert, as Administrator of the company, hereby declare that following mentioned products meet the provisions of the Council Regulation EU 2017/745 covering medical devices & Council Regulation 2016/425 covering Personal Protective Equipment. All documentation is controlled & retained on company premises. This declaration of conformity is issued under the sole responsibility of Roundten Europe SL.

Basic UDI-DI: 84356084

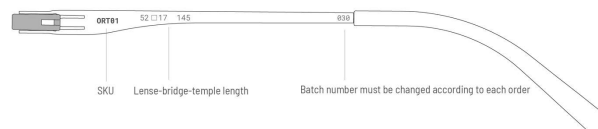
Product: Spectacle frames & spectacle frames with tinted lenses for the purposes to be used with corrective lenses non-tinted or tinted under the brand names Roundten.

Identification: UDI number (8) of the barcode & Reference number (5) on Label & Frames, see example below:

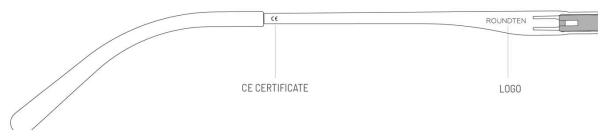


[ORT01]
ORTIZ 01

LASER MARKED / INSIDE MEASURES (RIGHT TEMPLE)



LASER MARKED / INSIDE LOGO (LEFT TEMPLE)



ROUNDTEN

ETERNAL FLEXTAL® EYEWEAR



Classification: Class I - Rule 1 Annex VIII

Standards Applied: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 10993-1:2009, EN ISO 12870:2018, ISO 12312-1:2013.

Notified Body NA

Place of Issue: Spain

Barcelona February 1st, 2022

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