

**EC Declaration of Conformity**  
**European Communities Council Regulation EU 2017/745**  
**Concerning Medical Devices**

The producer: Castellani SRL Unipersonale  
Via Fiume, n° 44  
32040, Domegge di Cadore (BL), Italy  
SRN: IT-MF-000030250

We hereby declare that the following mentioned products meet the provisions of the Council Regulation (EU) 2017/745 covering medical devices. All documentation is controlled and retained on company premises. This declaration of conformity is issued under the sole responsibility of manufacturer Castellani Srl Unipersonale.

**Basic UDI-DI:** 805750745CERTITGB

**Product:** Spectacle frames to be used with corrective lenses under the brand name *I Borghesi* and with the following commercial names:

IB9010 – IB9011 – IB9012 – IB9013 – IB9014 – IB9015 – IB9016 – IB9017 – IB9018 – IB9019 – IB9020 – IB9021 – IB9022 – IB9023 – IB9024 – IB9025 – IB9026 – IB9027 – IB9028 – IB9029 – IB9030 – IB9031 – IB9032 – IB9033 – IB9034 – IB9035 – IB9036 – IB9037 – IB9038 – IB9039 – IB9040 – IB9041 – IB9042 – IB9043 – IB9044 – IB9045 – IB9046 – IB9047 – IB8010 – IB8011 – IB8012 – IB8013 – IB8014 – IB8015 – IB9050 – IB9051 – IB9052 – IB9053 – IB9054 – IB9055 – IB9056

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

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

**Conformity Statement:** We herewith declare under sole responsibility that the above products meet the requirements of Regulation (EU) 2017/745, technical standard EN ISO 12870:201, EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 10993-1:2019, and have been affixed with the CE mark under the Regulation (EU) 2017/745 of the European Parliament and of the council of a April 2017



**Place of issue:** Italy  
**Date of issue:** 28/03/2023

**For Castellani SRL, the Sole Administrator**  
Castellani Marco

**Signature and stamp**  
CASTELLANI SRL UNIPERSONALE  
Minuterie ed Occhiali - Via Fiume, 44  
32040 DOMEgge DI CADORE (BL) ITALY  
Tel. +39 0435 520027 r.a. - Fax +39 0435 72083  
C.F. e P.I. 00924690258 - Reg. Imp. n. 2000-4892  
info@castellaniocchiali.it PEC: castellanisrl@ticertifica.it