

EN – English



DECLARATION OF CONFORMITY FOR OPTICAL FRAMES

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Inspects Limited, 7-10 Kelso Place, Upper Bristol Road, Bath, BA1 3AU, UK
SRN (Single Registration Number): GB-MF-000003388

EU Authorised Representative:

On Sight Services, Sociedade Unipessoal Lda, Rua Soares de Passos nº 10A e 10B,
1300-537 LISBOA, Portugal
SRN (Single Registration Number): PT-AR-000002821

Basic UDI-DI: 50550226OPTICALFRAMESQY Optical Frames (GMDN Code 32816/ EMDN XXXX)

Product Name/ model:	EAN (SKU):
BIO-1034-104	5055022656679
BIO-1034-105	5055022656686
BIO-1034-172	5055022656693

Standard or Technical Reference: BS EN ISO 12870:2018

BS EN 12472:2020

BS EN 16128:2015

Applicable Regulation: 2017/745/EEC Medical Devices Regulation- Class 1
REACH Regulation (EC) 1907/2006

This declaration will be translated into a language appropriate to the country destination of the product, copies can be obtained online, following the link: <https://inspecs.com/conformity-declaration/> or request from compliance@inspecs.com. We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge. All supporting documentation is retained at the premises of the manufacturer.

Signed for and on behalf of Inspects Limited

Bath, United Kingdom, Date of signing: 07 September 2023


Mr Robin Totterman
CEO


Mrs Amy Steen
MDR Responsible Person