

**C.O.I.**

**COMPAGNIA OTTICA ITALIANA Srl**

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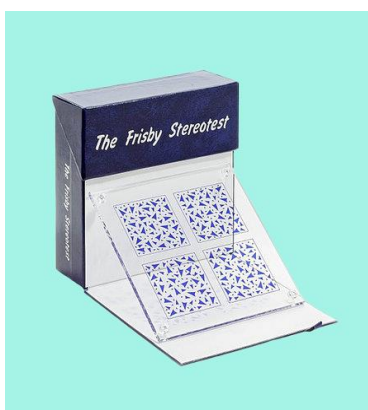
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## FRISBY STEREO TEST 3 tavole

codice: 63.020.00

### SCHEMA TECNICA

Realizzato nel rispetto delle norme generali del Regolamento Dispositivi Medici (UE) 2017/745 (MDR)



test ambientale - formato da figure disposte in ordine e dimensioni casuali su tre tavole in plexiglass con diversi spessori - il test riporta parte dell'immagine spostata dal piano mediante lo spessore di una lastra in plexiglas, la quale conferisce il senso di profondità.

Profondità da 5 a 600 sec arc.

non richiede l'uso di occhiali o dispositivi particolari.

DICHIARAZIONE DI CONFORMITÀ **CE**

La sottoscritta C.O.I. Srl- COMPAGNIA OTTICA ITALIANA di Ticozzelli Tico & Spirella - Via Paganini, 10 – 20131 Milano

Dichiara che il prodotto 63.020.00 FRISBY STEREO TEST 3 tavole

è conforme al:

**REGOLAMENTO DISPOSITIVI MEDICI (UE) 2017/745 (MDR) - DISPOSITIVI  
MEDICI DI CLASSE I**

aggiornato al 09/2023

**Statement of Self-Declaration of Conformity with UK Rules  
for Class 1 Medical Devices**

We STEREOTEST LTD of 8 Garden City, Thame, OX9 3NT certify that the products described below are in conformity with the applicable provisions of the UK Government's Medical Devices Regulations for affixing the mark of UKCA (UK Conformity Assessed) taking into account the intended purpose(s) and mode(s) of action of the UK's Medical Devices Regulations.

**FRISBY NEAR STEREOTEST (FNS)  
FOR BOTH 3-PLATES AND 1 or 2-PLATE POCKET VERSIONS**

The FNS is device falling within MDD 93/42/EEC Class 1 whose function is to assess stereoacuity at near viewing distances (30-150cm). The patient is shown a transparent acrylic plate on which are printed random element patterns. The elements are of triangular shape and are arranged in four quadrants. The patient is asked to find the quadrant that contains a roughly circular target shape whose elements appear at a different depth from all other elements on the plate. The depth difference arises from the target elements being printed on one side of the plate and all other elements on the other side of the plate. Hence the thickness of the plate determines the size of the depth difference between the target and the other elements. There are three plates provided in the 3-plates version, one each of thicknesses 6mm, 3mm and 1.5mm. The thinner the plate the smaller the binocular disparity of the target. Also, test viewing distance alters the size of the binocular disparity of the target. Finding the smallest disparity that the patient can reliably detect forms the basis of the measured stereoacuity.

The Pocket version of this test comprises either a single 6mm plate or both 6 and 3mm plates, and each plate has two side-by-side patches of elements, rather than the 4 patches in the 3-plate version. The device is not powered in any way and so it does not require batteries or connection to a mains power supply.

The suppliers of our acrylic plates, printing ink, and cardboard packing box have provided statements which we have lodged in a Technical File as required by the Regulations, declaring that their products are REACH compliant.

The FNS falls within Class I of the MHRA generic device code, Ophthalmic section, reference code F9 (Sight testing devices) and is eligible for self-declaration of conformity for Class 1 medical Devices. The existing CE mark can also be shown on the product along with the UKCA mark until 2023.

Responsible Person Professor J P Frisby Director, Stereotest Ltd



Signature of the Responsible Person Date 6 June 2022

