

EU DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A. (single registration number (SRN): IT-MF-000011004), with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milan, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Product and trade name	Product code	Basic UDI-DI
GIMA TEST FOR COLOUR DEFICIENCY - 10 plates - paediatric	31286	8023279Z1212019900000000YY
GIMA TEST FOR COLOUR DEFICIENCY - 15 plates - adult - new numbers	31288	8023279Z1212019900000000YY

Intended purpose: Intended to support the diagnosis of congenital color blindness.

Product and trade name	Product code	Basic UDI-DI
SNELLEN OPTOMETRIC CHART - 3 m - 23x35.5 cm	31301	8023279Z1212019900000000YY
TUMBLING "E" OPTOMETRIC CHART - 6 m - 23x35.5 cm	31302	8023279Z1212019900000000YY
SNELLEN OPTOMETRIC CHART - 6 m - 23x35.5 cm	31303	8023279Z1212019900000000YY
SLOAN OPTOMETRIC CHART - 6 m 23x35.5 cm	31304	8023279Z1212019900000000YY
TUMBLING "E" OPTOMETRIC CHART - 6 m - 28x56 cm	31307	8023279Z1212019900000000YY
TRADITIONAL SNELLEN OPTOMETRIC CHART - 6 m - 28x56 cm	31308	8023279Z1212019900000000YY
MIXED DECIMAL OPTOMETRIC CHART - 3 m - 28x56 cm	31309	8023279Z1212019900000000YY
EWING ILLITERATE OPTOMETRIC CHART - 6 m - 28x56 cm	31310	8023279Z1212019900000000YY
LOGMAR SLOAN near vision chart - 40 cm - 18x23 cm	31311	8023279Z1212019900000000YY

Intended purpose: Intended for determining the quality of distance vision and determining visual acuity.

risk class I (not sterile), in accordance with the rule 1 set out in Annex VIII of the Regulation (EU) 2017/745 (MDR), declares, under its sole responsibility, that this device:

- complies with the Regulation (EU) 2017/745 (MDR);
- Common Specifications have not been used for the compliance of the above medical device.

Gessate, 22/07/2026

GIMA S.p.A.
The Legal Representative
(Nicola Manzoni)

