

EC DECLARATION OF CONFORMITY

(pursuant to Article 19 and Annex IV of Regulation (EU) 2017/745)

The undersigned Stefano Fulchir

in his capacity as Chief Executive Officer of the company: iVision Tech S.p.A.

with registered office at: Via Via Pontaccio, 10 - 20121 Milan (MI) - Italy

VAT No. / Tax Code: 05103540265

DECLARES

under his own responsibility that the following medical device complies with the applicable requirements of Regulation (EU) 2017/745:

Commercial name of the device: **ISEE ONE**

Model / Product code: **ISEE ONE**

Device class: **Class I**

CND code: **Y210399 - Corrective optical devices or optical aids - Other**

UDI-DI: 805259044ISEEDM

Intended use: **Wearable electronic device designed to support the mobility and independence of visually impaired persons. It is intended for indoor use, in combination with other traditional mobility aids (e.g. cane).**

The device complies with the essential safety and performance requirements of Annex I of Regulation (EU) 2017/745 and refers to the following harmonised standards and technical standards:

- EN ISO 14971 - Risk management
- EN ISO 15223-1 - Symbols for labelling
- EN ISO 10993 - Biological evaluation of materials

The device has been designed, manufactured and verified in accordance with the technical documentation prepared according to Annexes II and III of Regulation (EU) 2017/745.

Place and date: Milan, 29 April 2026

Signature: _____

Stefano Fulchir

Chief Executive Officer - iVision Tech S.p.A.