

## Certificate of CE-Notification

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, **CEpartner4U BV** agrees to perform all duties and responsibilities as the Authorized Representative for

### **Artificial Learning Systems India Private Limited**

**1665/A, 2nd Floor, 14th Main, Sector 7,**

**HSR Layout, Bangalore- 560102**

**India**

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received the manufacturer's medical device registrations by CEpartner4U as listed on the product list attached to the manufacturer's Declaration of Conformity:

#### **Device group: DRISTi V1.1**

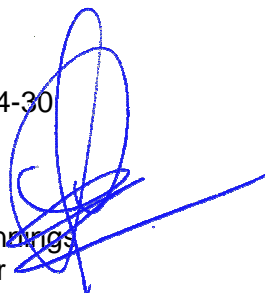
DRISTi is designed to capture a patient profile and associated medical images of the patient. The product analyzes the medical images of the patient using deep neural network and Deep Learning/Machine Learning. The product applies Artificial Intelligence algorithms to detect the presence of Diabetic Retinopathy.

**DRISTi V1.1 was registered with Dutch Competent Authorities and consequently these MDD devices are entered in EUDAMED by Dutch Competent Authorities**

The manufacturer has provided CEpartner4U with all necessary documentation, together with an appropriate Declaration of Conformity that the medical devices fulfil the essential requirements of Directive 93/42/EEC.

2018-04-30

AM Pennings  
Director



**C e p a r t n e r 4 U**

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