

EU DECLARATION OF CONFORMITY i-SEE LITE

Manufacturer Details: Rehan Electronics Ltd.

Brunswick Row, Aughrim Road,

Carnew,

Co. Wicklow Y14 NY60,

Ireland.

SRN Mfg. (Single Registration Number): IE-MF-000014745

Authorized Representative details: N/A (Not Applicable)

SRN A.R. (Single Registration Number): N/A

Basic UDI-DI: 539151347P0047F

Product(s): i-See Lite

Product Ref.: 2000-20-0005I-22W

Intended Purpose: Assistive technology for compensation of visual impairments and reading

disabilities.

Risk Classification: Class 1 – Rule 1

Common Specification: Not Applicable

Notified Body Name: Not Applicable

Notified Body Address: Not Applicable

Notified Body Identification No.: Not Applicable

Conformity Assessment Route: MDR 2017/745 Annex II & Annex III

This declaration of conformity is issued under the sole responsibility of Rehan Electronics Ltd. We hereby declare that the product specified above meets the provision of the Regulation (EU) MDR 2017/745 for medical devices and is in conformity with Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Signature:

Place: Carnew, Ireland
Date: 03/02/2023
Name: Seamus Doyle
Function: Director/PRRC

Rehan Electronics Ltd.