

DECLARATION OF CONFORMITY

Manufacturers name: *LVI Low Vision International AB*

Manufacturers Address: *Verkstadsgatan 5
S-352 46 Växjö
Sweden*

Web: *http://www.lviglobal.se*

SRN (Single Registration Number): *SE-MF-000004178*

Basic UDI-DI (GMN): *7330724MLSEC*

Brand name or trademark: *MagniLink*

Product code: ***MLS-HD-2, MLS-FHD-2***

Classification: *Class 1*

Type of equipment: *Reading Aid*

Conformity assessment route: *LVI Low Vision International AB uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

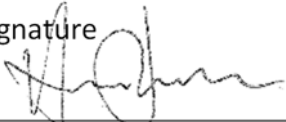
Class [1]: EC conformity declaration according to Annex I + Annex II +Annex VII*

This declaration of conformity is issued under the sole responsibility of LVI Low Vision International AB. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 9001 issued by Intertek. All supporting documentation is retained at the premises of the manufacturer.

Manufacturer

Manufacturer's authorized representative

Date
20-05-2021

Signature


Position
Managing Director

Clarification
Henrik Blomdahl