

# EU Declaration of Conformity

## Manufacturer:

ZYRLO, LLC.  
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United States of America  
Tel.: +1 800-600-8569

## European Authorized Representative:

ULTRACIFRA, UNIPessoal Lda.  
R. José Saramago 5A, 1675-180 Pontinha  
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## Product:

Electronic Text-to-Speech Reader "HARK Reader" (see Table 1 for Product List).

Basic UDI-DI of the Text-to-Speech reader is PP13175HARK10.

The "HARK Reader" is an electronic text-to-speech device for people who are blind or visually impaired, and is classified as a Class I Medical Device according to Annex VIII of the MDR, Rules 1 and 13.

Conformity assessment procedure for CE Marking: Medical Device Regulation (EU) 2017/745, according to Annexes II and III.

## Product Conformity:

We, Zirlo, LLC, declare under our sole responsibility that the product "Hark Reader", when used and operated according to the User Manual instructions, is in conformity with:

- Medical Device Regulation (EU) 2017/745.
- Low Voltage Directive 2014/35/EU.
- Electromagnetic Compatibility Directive 2014/30/EU.
- Radio Equipment Directive 2014/53/EU.
- Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU.
- Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive 2017/2102 amending Directive 2011/65/EU.

## Additional Information:

The following harmonized standards have either been referred to or been complied with in part or in full as relevant:

- ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes.
- EN 14971:2019 - Medical Devices - Application of Risk Management.
- EN 62368-1:2014 / AC:2015.
- EN 55032:2015 / A11:2020.
- EN 55035:2017 / A11:2020.
- EN 61000-3-3:2013.



**Date of the first Declaration of Conformity:**

See table 1 for Product List.

**GMDN-Code:**

17947 – video assistive reading device.

**This Declaration of Conformity is issued under the sole responsibility of the manufacturer:**

**Zirlo, LLC**

(Manufacturer Name)

**52, Tanbark Rd, Sudbury, MA 01776, United States of America**

(Manufacturer Address)

**Leon Reznik / General Manager**

(Name/Position)

**52, Tanbark Rd, Sudbury, MA 01776, United States of America**

(Place)

**August 1, 2024**

(Date)



(Signature)

**Table 1 – Product List**

<b>Product Name / Trade Name</b>	<b>Product Code / Reference</b>	<b>Basic UDI-DI</b>	<b>Risk Class / Rule</b>	<b>Date of first CE Marking</b>
HARK Reader	HARK-006	PP13175HARK10	Class I, Rules 1 and 13	September 1, 2022
HARK Reader	HARK-007	PP13175HARK10	Class I, Rules 1 and 13	January 29, 2024
HARK Reader	HARK-009	PP13175HARK10	Class I, Rules 1 and 13	August 1, 2024