EU DECLARATION OF CONFORMITY

1) Manufacturer:

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3) Product:

See Appendix

4) The product described above is in conformity with:

Title	Document No.
Medical Device Regulation	2017/745
Waste Electrical and Electronic Equipment (WEEE)	2012/19/EU
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)	2011/65/EU and its latest amendment 2017/2102
Radio Equipment Directive (RED)	2014/53/EU

5) Basic UDI-DI

The Basic UDI-DI of the Electronic Magnifiers is 83061100003JD.

6) Additional information

Conformity assessment procedure for CE marking: Medical Device Regulation 2017/745, Annexes II and III.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:
TECHNOLOGIES HUMANWARE INC.

Drummondville, Canada; 2021-11-02

Louis-Philippe Massé
Vice-President Product Innovation

Appendix

List of devices.

Device name	Reference ([REF])	Risk class / rule[1]	First date of CE-compliance
Explorē 5 Handheld Electronic Magnifier	FGEX-1000 FGEX-1012	Class I / Rules 1 and 13	2021-05-03
Explorē 8 Handheld Electronic Magnifier	FGEX-1016	Class I / Rules 1 and 13	2021-05-03
Explorē 12 Handheld Electronic Magnifier	FGEX-1020 FGEX-1022	Class I / Rules 1 and 13	2021-11-21
Reveal 16 Full HD Digital Magnifier	FGPG-1300 FGPG-1302	Class I / Rules 1 and 13	2021-05-03
Reveal 16i Full HD Digital Magnifier	FGPG-1304 FGPG-1305	Class I / Rules 1 and 13	2021-05-03
Connect 12 Electronic Magnifier	FGPG-1205 FGPG-1218 FGPG-1219 FGPG-1222 FGPG-1223 FGPG-1224	Class I / Rules 1 and 13	2021-05-03

[1] See risk classification in Medical Device Regulation, annex VIII