

	<i>EU Declaration of Conformity</i>	Document:DOC-003
		Version 00
		Page: 1 of 2

EU DECLARATION OF CONFORMITY

1) Manufacturer:

TECHNOLOGIES HUMANWARE INC.
1800 rue Jean-Berchmans-Michaud,
Drummondville, Quebec J2C 7G7
CANADA
Tel: +1 819 471 4818
Fax : +1 819 471 4828

2) European authorized representative:

CEpartner4U BV
Esdoornlaan 13
3951 DB Maarn
The Netherlands
Tel: +31.343.442.524
Fax: +31.6.516.536.26
www.cepartner4u.com
office@cepartner4u.com

3) Product:

See Appendix

4) The product described above is in conformity with:

<u>Title</u>	<u>Document No.</u>
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 (RoSH)	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; 2021-05-17



Pierre Hamel
Vice-President Research and Development

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
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