

EU DECLARATION OF CONFORMITY

1) Manufacturer:

TECHNOLOGIES HUMANWARE INC.
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2) European authorized representative:

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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
Radio Equipment Directive (RED)	2014/53/EU

5) Basic UDI-DI

The Basic UDI-DI of the Braille Products is 83061100001J9.

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
BrailleNote Touch 18 Plus	FGBT-1105	Class I / Rules 1 and 13	2021-05-03
BrailleNote Touch 32 Plus	FGBT-1104	Class I / Rules 1 and 13	2021-05-03
Mantis Q40	FGBR-1104 FGBR-1105 FGBR-1106	Class I / Rules 1 and 13	2021-05-03
BrailleOne	FGBR-1102	Class I / Rules 1 and 13	2021-05-03
Brailliant BI 20X	FGBR-1018	Class I / Rules 1 and 13	2021-05-03
Brailliant BI 40X	FGBR-1017	Class I / Rules 1 and 13	2021-05-03

¹ See risk classification in Medical Device Regulation, annex VIII