EU DECLARATION OF CONFORMITY

1) Manufacturer:

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3) Product:

See Appendix

4) All products described above is in conformity with:

Title	Document No.
Medical Device Regulation (MDR)	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
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; 2026-09-01

Louis-Philippe Massé
Vice-President Products Innovation

Appendix

List of devices.

Device name (model)	Reference ([REF])		Risk class / rule[1]	First date of CE-compliance	Radio Module
BrailleNote evolve 32 (BNE632) 32GB	FGBE-0001 FGBE-0002 FGBE-0003 FGBE-0004 FGBE-0005 FGBE-0006	FGBE-0013 FGBE-0014 FGBE-0015 FGBE-0016 FGBE-0017	Class I / Rules 1 and 13	2026-09-01	AX210.NGWG.NV nRF52832-MS50SFA1
BrailleNote evolve 20 (BNE620) 32GB	FGBE-0007 FGBE-0008 FGBE-0009 FGBE-0010 FGBE-0011 FGBE-0012	FGBE-0018 FGBE-0019 FGBE-0020 FGBE-0021 FGBE-0022	Class I / Rules 1 and 13	2026-09-01	AX210.NGWG.NV nRF52832-MS50SFA1
BrailleNote evolve 40 (BNE640) 32GB	FGBE-0023 FGBE-0024 FGBE-0025 FGBE-0026 FGBE-0027 FGBE-0028	FGBE-0029 FGBE-0030 FGBE-0031 FGBE-0032 FGBE-0033	Class I / Rules 1 and 13	2026-09-01	AX210.NGWG.NV nRF52832-MS50SFA1
BrailleNote evolve 32 (BNE632) 16GB	FGBE-0034 FGBE-0035 FGBE-0036 FGBE-0037 FGBE-0038 FGBE-0039	FGBE-0046 FGBE-0047 FGBE-0048 FGBE-0049 FGBE-0050	Class I / Rules 1 and 13	2026-09-01	AX210.NGWG.NV nRF52832-MS50SFA1
BrailleNote evolve 20 (BNE620) 16GB	FGBE-0040 FGBE-0041 FGBE-0042 FGBE-0043 FGBE-0044 FGBE-0045	FGBE-0051 FGBE-0052 FGBE-0053 FGBE-0054 FGBE-0055	Class I / Rules 1 and 13	2026-09-01	AX210.NGWG.NV nRF52832-MS50SFA1
BrailleNote evolve 40 (BNE640) 16GB	FGBE-0056 FGBE-0057 FGBE-0058 FGBE-0059 FGBE-0060 FGBE-0061	FGBE-0062 FGBE-0063 FGBE-0064 FGBE-0065 FGBE-0066	Class I / Rules 1 and 13	2026-09-01	AX210.NGWG.NV nRF52832-MS50SFA1

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

Complies to:

Radio Equipment Directive (RED) 2014/53/EU by application of:

Health and Safety (Article 3.1(a) of the RED)

EN 62368-1:2024+A11:2024
EN 62209-1528:2021
EN 50663:2017
EN 50566:2017+A1:2023

EMC (Article 3.1(b) of the RED)

EN 55032:2015+A1:2020
EN 55035:2017+A11:2020
EN 61000-3-2:2019+A2:2024
EN 61000-3-3:2013+A2:2021
EN 301 489-1 v2.2.3
EN 301 489-3 v2.3.2
EN 301 489-17 v3.3.1

Spectrum (Article 3.2 of the RED)

EN 300 330 v2.1.1
EN 300 328 v2.2.2
EN 301 893 v2.1.1
EN 300 440 v2.2.1

Medical Device Regulation (MDR) 2017/745 by application of:

EN ISO 14971:2019
EN 62304:2006 + AMD1:2015
Annex C of EN 12182:2012

Device name (model)	Reference ([REF])	Risk class / rule[2]	First date of CE-compliance	Radio Module
BrailleOne (BR20)	FGBR-1102	Class I / Rules 1 and 13	2021-05-03	6223A-SRD
Brailliant BI 20X (BI20) [3]	FGBR-1018 FGBR-1018GOV FGBR-1030	Class I / Rules 1 and 13	2021-05-03	6223A-SRD

Complies to:
Radio Equipment Directive (RED) 2014/53/EU by application of:

Health and Safety (Article 3.1(a) of the RED)
EN 62368-1:2014+A11:2017
EN62479:2010, EN 50566:2017, EN62209-2:2010 and IEC62209-2:2010

EMC (Article 3.1(b) of the RED)
EN 55032:2015/A11:2020
EN 55035:2017/A11:2020
EN 61000-3-2:2014
EN 61000-3-3:2013
EN 301 489-1 v2.2.1
EN 301 489-17 v3.2.0

Spectrum (Article 3.2 of the RED)
EN 300 328 v2.2.2

Medical Device Regulation (MDR) 2017/745 by application of:
EN ISO 14971:2019
EN 62304:2006 + AMD1:2015
Annex C of EN 12182:2012

[2] See risk classification in Medical Device Regulation, annex VIII
[3] Model BI20 is the same component as BR20. The base software is different and comes in 3 pre-loaded (REF model) options. Model BI20 was created after test reports have been completed. Humanware claims BI20 should be considered a variant of the BR20 and can use the test reports.

Device name (model) [4]	Reference ([REF]) [5]	Risk class / rule[6]	First date of CE-compliance	Radio Module
Mantis Q40		Class I / Rules 1 and 13	2021-05-03	6223A-SRD
(BRQT40)	FGBR-1104			
(BRQT40AZ)	FGBR-1105			
(BRQT40QZ)	FGBR-1106			
(BRQT40)	FGBR-1104GOV			
(BRQT40AZ)	FGBR-1105GOV			
(BRQT40QZ)	FGBR-1106GOV			

Complies to:
Radio Equipment Directive (RED) 2014/53/EU by application of:

Health and Safety (Article 3.1(a) of the RED)
EN 62368-1:2014+A11:2017
EN62479:2010, EN 50566:2017, EN62209-2:2010 and IEC62209-2:2010

EMC (Article 3.1(b) of the RED)
EN 55032:2015/A11:2020
EN 55035:2017/A11:2020
EN 61000-3-2:2014
EN 61000-3-3:2013
EN 301 489-1 v2.2.3
EN 301 489-17 v3.2.2

Spectrum (Article 3.2 of the RED)
EN 300 328 v2.2.2

Medical Device Regulation (MDR) 2017/745 by application of:
EN ISO 14971:2019
EN 62304:2006 + AMD1:2015
Annex C of EN 12182:2012

[4] Models BRQT40AZ and BRQT40QZ uses the same components as BRQT40. Only the pad printing on the keyboard is different. Models ending with AZ and QT was created after test reports have been completed. Humanware claims BRQT40AZ and BRQT40QZ should be considered a variant of the BRQT40 and can use the test reports.
[5] [REF] ending with GOV have a different Software pre-loaded in the device.
[6] See risk classification in Medical Device Regulation, annex VIII

Device name (model)	Reference ([REF]) [7]	Risk class / rule[8]	First date of CE-compliance	Radio Module
Brailliant BI 40X (BI400)	FGBR-1017 FGBR-1017GOV FGBR-1029	Class I / Rules 1 and 13	2021-05-03	ST60-SIPT

Complies to:
Radio Equipment Directive (RED) 2014/53/EU by application of:

Health and Safety (Article 3.1(a) of the RED)
EN 62368-1:2014+A11:2017
EN 62311:2020 and EN 62479:2010

EMC (Article 3.1(b) of the RED)
EN 55032:2015/A11:2020
EN 55035:2017/A11:2020
EN 61000-3-2:2014
EN 61000-3-3:2013
EN 301 489-1 v2.2.3
EN 301 489-17 v3.2.3

Spectrum (Article 3.2 of the RED)
EN 300 328 v2.2.2
EN 301 893 v2.1.1

Medical Device Regulation (MDR) 2017/745 by application of:
EN ISO 14971:2019
EN 62304:2006 + AMD1:2015
Annex C of EN 12182:2012

[7] Same models used. The different [REF] indicates different software pre-loaded..
[8] See risk classification in Medical Device Regulation, annex VIII

Device name (model)	Reference ([REF])	Risk class / rule[9]	First date of CE-compliance	Radio Module
Monarch (BNP480)	FGBR-1201	Class I / Rules 1 and 13	2024-10-01	ST60-SIPT

Complies to:
Radio Equipment Directive (RED) 2014/53/EU by application of:

Health and Safety (Article 3.1(a) of the RED)
EN 62368-1:2014+A11:2017
EN 62311:2020 and EN 62479:2010

EMC (Article 3.1(b) of the RED)
EN 55032:2015/A11:2020
EN 55035:2017/A11:2020
EN 61000-3-2:2014
EN 61000-3-3:2013
EN 301 489-1 v2.2.3
EN 301 489-17 v3.2.3

Spectrum (Article 3.2 of the RED)
EN 300 328 v2.2.2
EN 301 893 v2.1.1

Medical Device Regulation (MDR) 2017/745 by application of:
EN ISO 14971:2019
EN 62304:2006 + AMD1:2015
Annex C of EN 12182:2012

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