

EU DECLARATION OF CONFORMITY

1) Manufacturer:

TECHNOLOGIES HUMANWARE INC.
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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
Low Voltage Directive (LVD)	2014/35/EU
Electromagnetic Compatibility Directive (EMC)	2014/30/EU

5) Basic UDI-DI

The Basic UDI-DI of the Digital Talking Book Players is 83061100002JB.

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
Victor Reader Stratus4 (402VR)	95-STRATUS4CE-DEDE 95-STRATUS4CE-DKDA 95-STRATUS4CE-FRFR 95-STRATUS4CE-NLNL 95-STRATUS4CE-NONO 95-STRATUS4CE-SESV 95-STRATUS4CE-UKEN	Class I / Rules 1 and 13	2021-05-03
Victor Reader Stratus12 (403VR)	95-STRATUS12CE-DEDE 95-STRATUS12CE-DKDA 95-STRATUS12CE-FRFR 95-STRATUS12CE-NLNL 95-STRATUS12CE-NONO 95-STRATUS12CE-SESV 95-STRATUS12CE-UKEN	Class I / Rules 1 and 13	2021-05-03
Victor Reader Stratus4 M (412VR)	95-STRATUS4MCE-DEDE 95-STRATUS4MCE-DKDA 95-STRATUS4MCE-FRFR 95-STRATUS4MCE-NLNL 95-STRATUS4MCE-NONO 95-STRATUS4MCE-SESV 95-STRATUS4MCE-UKEN FGSS-1057 FGSS-1071 FGSS-1074 FGSS-1075 FGSS-1076	Class I / Rules 1 and 13	2021-05-03

¹ See risk classification in Medical Device Regulation, annex VIII

Device name	Reference ([REF])	Risk class / rule ¹	First date of CE-compliance
Victor Reader Stratus12 M (413VR)	95-STRATUS12MCE-DEDE 95-STRATUS12MCE-DKDA 95-STRATUS12MCE-FRFR 95-STRATUS12MCE-FRFR 95-STRATUS12MCE-NLNL 95-STRATUS12MCE-NONO 95-STRATUS12MCE-SESV 95-STRATUS12MCE-UKEN FGSS-1056 FGSS-1072 FGSS-1073 FGSS-1077 FGSS-1078	Class I / Rules 1 and 13	2021-05-03
Victor Reader Stratus4 I (422VR)	FGSS-1046 FGSS-1047 FGSS-1059 FGSS-1060	Class I / Rules 1 and 13	2021-05-03
Victor Reader Stratus12 I (423VR)	FGSS-1044 FGSS-1045 FGSS-1048 FGSS-1058	Class I / Rules 1 and 13	2021-05-03
Victor Reader Stream (503VRC)	95-STREAM2CE-DEDE 95-STREAM2CE-DKDA 95-STREAM2CE-ESES 95-STREAM2CE-UARU 95-STREAM2CE-NLNL 95-STREAM2CE-SESV 95-STREAM2CE-UKEN FGST-1017 FGST-1019	Class I / Rules 1 and 13	2021-05-03