Ministry of Health, Welfare and Sport CIBG P.O. Box 16114 2500 BC The Hague THE NETHERLANDS



## FREE SALES CERTIFICATE

The undersigned herewith declares that, according to the Decree on Medical Devices, which is based on Regulation (EU)  $2017/745^1$ ,

Cepartner4u B.V. Esdoornlaan 13 3951 DB Maarn THE NETHERLANDS

acts as authorised representative of the manufacturer.

The manufacturer:

Technologies HumanWare Inc. 1800 rue Jean-Berchmans-Michaud, J2C 7G7 Drummondville, Quebec CANADA

which has its authorized address in the Netherlands and is authorized to manufacture and/or supply the medical device/devices mentioned below:

## See product list

This device/these devices, that has/have a CE-marking, may be placed on the Dutch market and on the markets of the other Member States of the European Union. This Free Sales Certificate may only be used for export outside the European Union.

The present Free Sales Certificate is drawn up at the request of the interested party in order to be submitted to the Health Authorities of EGYPT.

This Free Sales Certificate is valid up to and including December 6, 2029.

The Hague, January 2, 2025

On behalf of the Minister for Health, Welfare and Sport, Farmatec | CIBG Dr. M.L.van c Mr. M.J. van de Velde Head of Department

Our reference: 20244392 Certificate number: 47101

<sup>&</sup>lt;sup>1</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EE.



Device group 1: Braille devices			
Device name	Part number	Risk class	EMDN
BRQT40	FGBR-1104	Class I / Rules 1 and 13	Y210999
BRQT40AZ	FGBR-1105	Class I / Rules 1 and 13	Y210999
BRQT40QZ	FGBR-1106	Class I / Rules 1 and 13	Y210999
BRQT40	FGBR-1104GOV	Class I / Rules 1 and 13	Y210999
BRQT40AZ	FGBR-1105GOV	Class I / Rules 1 and 13	Y210999
BRQT40QZ	FGBR-1106GOV	Class I / Rules 1 and 13	Y210999
BNT518	FGBT-1105	Class I / Rules 1 and 13	Y210999
BNT532	FGBT-1104	Class I / Rules 1 and 13	Y210999
BR20	FGBR-1102	Class I / Rules 1 and 13	Y210999
	FGBR-1018	Class I / Rules 1 and 13	Y210999
BI20	FGBR-1018GOV		
	FGBR-1030		
	FGBR-1017	Class I / Rules 1 and 13	Y210999
BI400	FGBR-1017GOV		
	FGBR-1029		
BNP480	FGBR-1201	Class I / Rules 1 and 13	Y210999

Device group 2: Dig	ital talking books		
Device name	Part number	Risk class	EMDN
Device name Victor Reader Stream V3 (603VRC)	Part number           FGST-1100           FGST-1101           FGST-1102           FGST-1103           FGST-1104           FGST-1105           FGST-1106           FGST-1107           FGST-1108           FGST-1109           FGST-1110	Risk class Class I / Rules 1 and 13	Y2127
	FGST-1111		

Device group 3: Electronic Magnifiers				
Device name	Part number	Risk class	EMDN	
Connect 12 Electronic Magnifier PGI-400	FGPG-1205	MAL 1434	and a set	
	FGPG-1218	1 CALA	A port	
	FGPG-1219	Class I / Dules 1 and 12	NOCO2	
	FGPG-1222	Class I / Rules 1 and 13	Velde X2/0603	
	FGPG-1223	20 1-300 5 Cm. 10	alth, Welfare or	
	FGPG-1224			

Device group 3: Electronic Magnifiers			
Device name	Part number	Risk class	EMDN
Connect 12 Electronic Magnifier Version 2.1 PGI-401	FGPG-1205SC FGPG-1246 FGPG-1218SC FGPG-1247 FGPG-1219SC FGPG-1223SC FGPG-1224SC FGPG-1222SC	Class I / Rules 1 and 13	Y210603
Explorē 5 Handheld Electronic Magnifier NOM-300	FGEX-1000 FGEX-1012	Class I / Rules 1 and 13	Y210603
Explorē 5 Handheld Electronic Magnifier NOM-301	FGEX-1023 FGEX-1024	Class I / Rules 1 and 13	Y210603
Explorē 8 Handheld Electronic Magnifier NOM-400	FGEX-1016	Class I / Rules 1 and 13	Y210603
Explorē 8 Handheld Electronic Magnifier NOM-400	FGEX-1025	Class I / Rules 1 and 13	Y210603
Explorē 12 Handheld Electronic Magnifier NOM-500	FGEX-1020 FGEX-1022	Class I / Rules 1 and 13	Y210603
Reveal 16 Full HD Digital Magnifier RVL-100 RVL-100XY	FGPG-1300 FGPG-1302	Class I / Rules 1 and 13	Y210603
Reveal 16i Full HD Digital Magnifier RVL-110 RVL-110XY	FGPG-1304 FGPG-1305	Class I / Rules 1 and 13	Y210603

Device group 4: Digital Assistant Products			
Device name	Part number	Risk class	EMDN
Stellar Trek	FGAB-0001	Class I / Rule 13	Y1299