EU Declaration of Conformity

For: SuperNova Magnifier and Screen Reader

SuperNova Magnifier and Speech

SuperNova Magnifier

Dolphin ScreenReader

Document Reference

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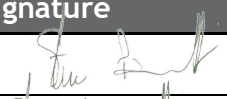
Document Approvals

Reviewed and Approved By:			
Print Name	**Position**	**Signature**	**Date**
Steve Bennett	Managing director		24/09/21
Steve Bennett	Managing director		20/01/22
Steve Bennett	Managing director		03/03/22

Document Revision History			
Rev #	**Author**	**Description of change**	**Date**
1	Manuel Martin	Create new document	24/09/21
2	Jane Brassington	Update EUAR, apply template	20/01/22
3	Jane Brassington	Add EUAR SRN	03/03/22

Appendix 01: EU Declaration of Conformity

European Communities Council Directive 93/42/EC concerning medical devices as amended by Regulation (EC) 2017/745.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

Section I – General Details

General Products Names:	SuperNova Magnifier and Screen Reader SuperNova Magnifier and Speech SuperNova Magnifier Dolphin ScreenReader
Manufacturer:	Dolphin Computer Access Ltd. Technology House, Blackpole Estate West, Worcester, WR3 8TJ, United Kingdom
Device GTIN:	5065007755006 5065007755013 5065007755020 5065007755044
Intended Use:	Supernova and Dolphin devices are software application programs designed to assist a person with a visual impairment to operate a computer, typically by providing magnification of the screen text/images and/or providing text-to-speech functionality.
Intended User:	Personal use
Medical Device Directive Category / Classification:	Software/ Class I
Notified Body:	Not applicable
CE Certificate Reference:	Not applicable
MDR Directive Conformity Assessment Route:	Annex III (EC Declaration of Conformity)
EU Authorised Representative:	Sensus Consulting Ltd The Black Church, St. Mary's Place, Dublin D07 P4AX Ireland
EUAR SRN:	IE-AR-000020337

Name:	Steve Bennett	Position:	Managing director
Signature:		Date:	03 Mar 2022 *(Format: dd mmm yyyy)*

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Section II – Applicable Standards

This present declaration is also in conformity with the following European and International standards:

Standard/Document Name	Description
93/42/EC	Medical Devices EU Council Directive (as amended by Regulation 2017/745/EU)
2017/745/EU	Medical Device Regulation in the European Union
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
IEC 62304:2006/ Amd. 1:2021	Medical Device Software. Software Lifecycle Processes
EN ISO 14155:2020	Clinical Investigation for Medical devices

Section III – Product Listing/Status

GTIN Code	Brand Name/Description	Device Status
5065007755006	SuperNova / SuperNova Magnifier and Screen Reader	Active
5065007755013	SuperNova / SuperNova Magnifier and Speech	Active
5065007755020	SuperNova / SuperNova Magnifier	Active
5065007755044	Dolphin / Dolphin ScreenReader	Active