

## EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

|                                                    |                                                                                                                                                          |
|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name and Address of the Manufacturer:</b>       | Solutions Radio BV<br>Kalfjeslaan 38, 2623AJ Delft<br>Netherlands                                                                                        |
| <b>SRN of the Manufacturer:</b>                    | NL-MF-000033412                                                                                                                                          |
| <b>Basic UDI-DI:</b>                               | 872089202620webboxJE<br>872089202620webboxJE                                                                                                             |
| <b>Product Description:</b>                        | Technical disability aid for listening to<br>spoken books, radiostations, spoken<br>subtitles, spoken websites, podcasts,<br>spoken date/time and voting |
| <b>Product Identification:</b>                     | Solutions Radio Webbox3, Daisybox and<br>Soundbox                                                                                                        |
| <b>Product-No.:</b>                                | See Annex I of this document                                                                                                                             |
| <b>Classification</b> (acc. to Annex VIII of MDR): | Class I                                                                                                                                                  |
| <b>Conformity Assessment Procedure:</b>            | Self-declaration acc. to Annex I,II, III in<br>Regulation (EU) 2017/745 on Medical<br>Devices                                                            |

On our sole responsibility, we hereby declare that the product(s) comply with the relevant provisions of the following Regulation and Directives:

### **Regulation (EU) MDR 2017/745 of the European parliament and of the Council on Medical Devices**

This declaration is valid until the next change of the product. Any modification of the medical device not authorized by us will invalidate this declaration.

# ANNEX I TO THE EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Signature:



.....  
[Name, Function] Richard Ham, Operations Manager  
[Place, Time] Delft December 19 2023

Products Covered:

| Trade Name               | Article No. |
|--------------------------|-------------|
| Solutions Radio Webbox3  | N/A         |
| Solutions Radio Daisybox | N/A         |
|                          |             |
|                          |             |