



EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Name and Address of the Manufacturer:	Solutions Radio BV Kalfjeslaan 38, 2623AJ Delft Netherlands
SRN of the Manufacturer:	NL-MF-000033412
Basic UDI-DI:	872089202620goboxV5, 872089202620goboxV5
Product Description:	Technical disability aid for spoken subtitles and aid for enlarged subtitles
Product Identification:	Solutions Radio Go-Box and Solutions Radio Vo-box
Product-No.:	See Annex I of this document
Classification (acc. to Annex VIII of MDR):	Class I, rule 13
Conformity Assessment Procedure:	Self-declaration acc. to Annex I, II, III in Regulation (EU) 2017/745 on Medical 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] *R. Ham Operations Manager*
[Place, Time] *Delft 29 Nov. 2023*

Products Covered:

Trade Name	Article No.
Solutions Radio Go-box	N/A
Solutions Radio Vo-box	N/A