

## EU DECLARATION OF CONFORMITY

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We, Headovation hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745.


The device(s) is/are Class I following Rule1 of Annex VIII of REGULATION (EU) 2017/745.

The following conformity assessment procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

*The following Standards have been used and in relation to which conformity is declared:*

- ISO 13485:2016
- ISO 14791:1019

The present declaration is in conformity with Regulation (EU) 2017/745

  
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Tel-Aviv 26/4/22

*Headovation's PRRC Signature*

*Ronit Sadeh*

## Annex - List of Devices Covered by the Declaration of Conformity

#	Commercial name/ Trade name	Model / Re or de r/ Ca tal og ue no. #	Description	Intended Purpose	Class	Classif icatio n rule applie d	BASIC UDI - DI	GMDN/EM DN code
1	<b>Headaloft</b>			Head support device for users who lack head control, attaches to any wheelchair or aid device equipped with a head rest	<b>I</b>	<b>1</b>	7290016145headovationsXB	<b>13356</b>
2	<b>Headaloft occipital support</b>		<b>A small cushion add to the HEADALOFT product</b>	<b>Add on cushion to headaloft product</b>	<b>I</b>	<b>1</b>	7290016145headovationsXB	<b>13356</b>

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