CERTIFICATE
OF
MDR NOTIFICATION

Ref. No.: KAS 0146-2022

Date: 22/02/2022

Order No.: GR 1452-2021

This is to certify that, according to the Regulation (EU) 2017/745 We, here at Obelis s.a. (O.E.A.R.C.) performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

name: HEADOVATIONS LTD

address: 3 Adirim St, Tel-Aviv, Israel

as stipulated and demanded by the aforementioned regulation

The Manufacturer declares that the Class I * device complies with the Regulation including all general safety and performance requirements.
The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Regulation (EU) 2017/745 article 52 requirements, including the EC Declaration of Conformity (according to Annex IV) confirming that their Class I medical device, as stipulated here below, is fulfilling the applicable requirements of the the Regulation (EU) 2017/745.

The notification of the following medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 21/02/2022 in compliance with the Regulation (EU) 2017/745.

Class I medical device: please see Annex A - List of Devices (1 Page, 1 device)

As of the 22/02/2022, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on this(ese) device;

- May place this device in the European Union and EEA territory,

G. ELKAYAM C.E.O
Obelis s.a. - O.E.A.R.C.
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Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*Also applicable to Class Is, Im and Ir
** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

* This is not a CE mark and is only provided as a template for informational purposes.

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Annex A - List of Devices

(REGULATION (EU) 2017/745 on medical devices)

#	Commercial Name	Short description and intended use	Device already on the EU market? (y/n)	How device is placed on market from 26 May 2021 (Art 120/MDR/procedure kit or system/custom-made)	GMDN Code	EMDN code	BASIC UDI - DI	Risk class	Classific. Rule
1.	Headaloft	Head support device for users who lack head control, attaches to any wheelchair or aid device equipped with a head rest	Y	MDR	13356	N/A	7290016145headovationsXB	I	1

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (Annex VII - REGULATION (EU) 2017/745)

Signature:

Date: 22/02/2022

Stamp:

G. ELKAYAM C.E.O.

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