Obelis GROUP

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Registered Adresss
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CERTIFICATE OF MDR NOTIFICATION

Reference No.: KAS 0438-2023 **Date:** 29/08/2023

Order No.: EU JC 0811-2022

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

Name: HEADOVATIONS LTD **Address:** 3 Adirim St, Tel-Aviv, 6918409, 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. with all the appropriate declarations as per the Regulation (EU) 2017/745 Article 52 requirements, including the EC Declaratoin of Conformity (according to Annex IV), confirming that their Class I medical device, as stipulated here below, is fulfilling the applicable requirements of the Regulation (EU) 2017/745.
The notification of the following medical device has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/745 on the 22/08/2023

MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (1 Device, 1 Page)

As of the 23/08/2023, and provided that the manufacturer will continue complying with the hereabove mentioned requirements*, he therefore:
- Is required to affix the CE marking on this device;
- May place this device on the European Union and EEA territory.

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

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

*This certificate will become void automatically upon termination of the EAR agreement or removal of the products from EARMandate

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Annex A - List of Devices

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

#	Commercial Name	Short description and intended use	How device is placed on market from 26 May 2021?	EMDN Code	GMDN Code	BASIC UDI - DI	Risk class & Classification Rule MDD	Risk class & Classification Rule MDR
1	HEADALOFT 360	An all-encompassing wheelchair headrest for users who lack head control and/or need head support.	MDR compliant	P099003	13356	7290016145 head3608B	Class I Rule 1	Class I Rule 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 VIII - REGULATION (EU) 2017/745)

Obelis s.a.
Date: 29/08/2023

Stamp:

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