

# CERTIFICATE

OF

## MDR NOTIFICATION

Ref. No.: FRA 0166-2022

Date: 25/02/2022

Order No.: AB 1665-2021

name: OPTOACOUSTICS LTD.

address: 17 Hanotea, 7316000, St Mazor ISRAEL

as stipulated and demanded by the aforementioned regulation

Class I medical devices:



G. ELKAYAM  
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**Mr. G. Elkayam CEO**

**Obelis sa**



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**Annex A - List of Devices**

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

#	Catalogue reference number	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	Classification Rule
1.	n/a	OptoACTIVE	Active MR Noise-Canceling Headphones	Y	MDR	n/a	Z1105	7290019141	I	1
2.	n/a	IMROC-IR	Infrared Interventional MR Communication System	Y	MDR	n/a	Z1105	7290019141	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)

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