Obelis GROUP

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CERTIFICATE OF MDR NOTIFICATION

Reference No.: CPCM 0295-2024 **Date:** 07/06/2024

Order No.: EU AB 2025-2021

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: DPE MEDICAL LTD. **Address:** PO Box 49, 9085500 Shoeva, Israel

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION:

The manufacturer declares that the Class I device(s) comply(ies) 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(s), as stipulated here below, is/are fulfilling the applicable requirements of the Regulation (EU) 2017/745.
The notification of the following medical device(s) has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/745 on the 10/06/2024

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

As of the 10/06/2024 , and provided that the manufacturer will continue complying with the hereabove mentioned requirements*, he therefore:
- Is required to affix the CE marking on this(ese) device(s);
- May place this(ese) device(s) 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 Authoritzed 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)

							Nomenclature			Risk class & Classification Rule	
#	Catalogue reference number	Commercial Name	Short description and intended use	Device already on the EU market?	Legacy Device (Y/N)	Does the product contain a medicinal product as per definition of Art.1.2 Directive 2001/83/EC?	EMDN Code	GMDN Code	BASIC UDI - DI	MDD	MDR
1	DST	DST8000	Device with adjustable stairs for physiotherapy.	No	MDR compliant	No	Z120602	-46339	++G535DSTMODELSRC	N/A	Class I Rule 1
	DSTP	DST8000 Pro		No	MDR compliant	No					
	DSTT	DST8000 Triple		No	MDR compliant	No					
	DSTTX	DST8000 Triple XL		No	MDR compliant	No					
	DSTTP	DST8000 Triple Pro		No	MDR compliant	No					
	DSTTPX	DST8000 Triple Pro XL		No	MDR compliant	No					
	DSTTS	DST Triple Sense		No	MDR compliant	No					

* 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: 07/06/2024

Stamp:

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