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CERTIFICATE OF MDR NOTIFICATION

Reference No.:

Order No.:

Date:

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:

Address:

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION:

The manufacturer declares that the

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.

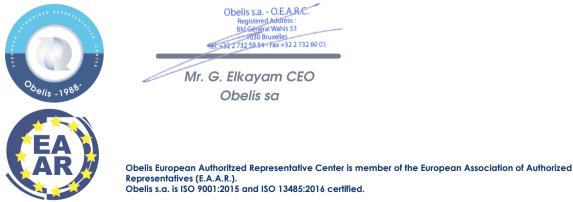
The notification of the following medical device(s) has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/745 on the **10/06/202**4

MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES

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.



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

Order No.: EU AB 2025-2021

Ref No.: CPCM 0295-2024

Annex A - List of Devices

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

			. 0	-			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	++G535DST MODELSRC	0	Class I Rule 1
	DSTP	DST8000 Pro		No	MDR compliant	No				-	
	DSTT	DST8000 Triple		No	MDP	No				z	
	DSTTX	DST8000 Triple XL			MDR	No					
	IUNIIP	DST8000 Triple Pro		No	MDR compliant	No				6	
	DSTTPX	DST8000 Triple Pro XL		No	MDR compliant	No					
	DSTTS	DST Triple Sense		No	MDR	No					

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* 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) 1988

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OBELIS S.A.

Date: 07/06/2024

Stamp:

Obelis s.a. - O.E.A.R.C. **Registered Address :** Bld Général Wahis 53 1030 Bruxelles Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Attachments – Annex A - ID# DOC11.15.0045-10 – 08/08/2023