

DPE-CE-2024-02.1

## **DECLARATION OF CONFORMITY**

According to regulation (EU) 2017/745 of the European Parliament and of the Council, Medical Device Regulation [MDR],

We, DPE Medical Ltd. P.O.B 49, Shoeva 90855, ISRAEL

Declare under our sole responsibility that the following non-sterile products under Class I:

**Dynamic Stair Trainer:** 

Models: DST8000; DST8000 Pro; DST8000 Triple, DST8000 Triple Pro; DST Triple Sense, Sense of Balance,

Meet the provisions of the Council MDR Directive concerning medical devices which apply to them.

The products are intended to be used for practicing stair and slope climbing skills.

Conformity assessment was performed according to the regulation.

The following standards were used to prove the products conformity with the essential requirements of the above directive:

EN ISO 13485

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

Obelis s.a. 34 Av. de Tervuren B-1040 Brussels, Belgium Phone: 32.2.732.59.54 Fax: 32.2.732.60.03 E-mail: mail@obelis.net Representative: Mr. Gideon ELKAYAM

<u>Summery</u>: Name of manufacturer - DPE Medical Ltd. Legal address: 49, Yefe Nof St., Shoeva, Israel Factory address: Yaholom St. 12, Har Tov 2, Beit Shemesh, Israel

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Signature:

Name: Mr. Daniel Orgal

Position: C.E.O Stamp:

18-Jul-2024 Shoeva Medical

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