

EU DECLARATION OF CONFORMITY

(in accordance with Annex IV of Regulation (EU) 2017/745 on medical devices)

1. Manufacturer

Name: Madglove Amsterdam BV

Registered trade name / trademark: Madglove Amsterdam

SRN: NL-MF-000047269

Address: De Boelelaan 1095-a (Unit 1A-08), 1081HV, Amsterdam, Netherlands

Authorised Representative: Madalina Antonia Maria Riurean (Chief Executive Officer) and Sitah Isabella Heijnen (Chief Product Officer)

2. Responsibility Statement

This declaration of conformity is issued under the sole responsibility of the manufacturer.

3. Basic UDI-DI

87208927173ASSIST558

4. Product Information

Product name: Madglove Assist

GTIN article codes: 8720892717313, 8720892717320, 8720892717337, 8720892717344, 8720892717351, 8720892717368, 8720892717375, 8720892717382, 8720892717399

Description: The Madglove Assist is a Class I non-invasive, non-sterile, non-measuring medical device (**Annex XX**) designed to aid in hand rehabilitation. The device's primary mechanism is to provide external support, encouraging finger extension, and correcting wrist posture.

Intended purpose: To stabilize the wrist, improve finger and thumb extension, and correct hand and finger positioning to support rehabilitation and enhance Activities of Daily Living (ADLs) in adults with upper limb and hand disabilities (including spasticity levels 1-3, Modified Ashworth Scale, weakness, limited movement control, or spasms).

5. Risk Class

The device is classified as Class I in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/745.

6. Conformity Statement

The device covered by this declaration is in conformity with Regulation (EU) 2017/745 and with any other applicable Union legislation.

7. Harmonised Standards / CS

References to relevant harmonised standards and common specifications applied:

- [e.g., EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 10993 series, etc.]

8. Notified Body Involvement

Not applicable (Class I non-sterile, no measuring function).

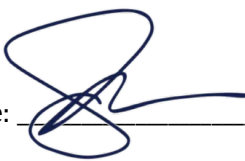
9. Additional Information

Not applicable.

10. Signatures

Place and date of issue: Amsterdam, Netherlands, 10.09.2025

Name and function of signatory 1: Madalina A.M. Riurean (CEO)

Signature: _____

Name and function of signatory 2: Sitah I. Heijnen (CPO)

Signature: _____