

2024-01-29

Declaration of Conformity

We: **Mego Afek AC Ltd., Located in Kibbutz Afek, 3004200, Israel**
EUDAMED SRN: IL-MF-000006982

Designate authorized representative: **MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany**, Phone +49 251 32266-61, www.mednet-eurep.com
EUDAMED SRN DE-AR-000000002

Hereby declare that the DoC issued under our sole responsibility and belongs to the distributed CE marked products specified in the annexed list and covered by the "CE Marking of Conformity Certificate", reference # 3902829CE01 initially issued on 2024-01-24, and delivered by DEKRA Certification B.V. Arnhem, the Netherlands Notified Body Identification Number 0344, and conform to the required information in accordance with Article 19 & Annex IV of the "EU Medical Device Regulation 2017/745 (MDR) as amended by Regulations EU 2020/561 & (EU) 2023/607.

In addition, we ensure and declare that the distributed CE marked products, as mentioned, are falling within Class IIa, and meet the provisions of the MDR which apply to them.

This declaration is based on the application of the Quality Management System approved for full quality assurance system in accordance with Annex IX (excluding sections 5 & 6) of the MDR. The conformity of the full quality assurance system set out in Annex IX is described in the said CE marking and Conformity Certificate issued and delivered by **DEKRA Certification B.V.**

This declaration is supported by the quality system certification based on the standards ISO 13485:2016, compliance certificate with reference # 3902512, initially issued on March 12, 2020 and delivered by DEKRA Certification B.V.

This declaration of conformity covers Therapeutic Pneumatic Compression Systems as specified in the product list (A+B) belonging to this declaration and is valid respectively for products concerned bearing the CE marking and manufactured at the following site: **Kibbutz Afek 3004200, Israel.**

On behalf of Mego Afek AC Ltd.:
2024-01-29

Tsvi Carniel	QA/RA Manager	Mego Afek AC Ltd. Kibbutz Afek, 3004200, Israel	
Name	Position	Address	Signature

MDR DoC Rev A 2024-01-29



MEGO AFEK AC Ltd.
Compression Therapy Systems

Product List A – Devices (Company Prefix 729010587)

Device description	Model	Basic UDI-DI	Product PN	Time related information		Notes
				From S/N	From date	
Lympha press Optimal Plus (EU) BT	912	729010587912D3	L10008C2-EU	02317	2020-11-30	① ②
Lympha press Optimal Plus (AU) BT			L10008C2-AU	02551	2020-12-23	① ② ③

Notes:

- ① The device is conformed to EU Medical Device Regulation 2017/745 (MDR) and respectively with the following International Electrotechnical Commission standards for Medical Electrical Equipment and the harmonized standards in the Official Journal of the European Union:
- EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020
IEC 60601-1:2005+A1:2012+A2:2020 (Ed. 3.2)
 - EN 60601-1-11:2015+A1:2020
IEC 60601-1-11:2015+A1:2020 (Ed. 2.1)
 - EN 60601-1-2:2015+A1:2020
IEC 60601-1-2:2014+AMD1:2020 (Ed. 4.1)
- ② The device is conformed with the provision of the Annex VI of European Directive Radio Equipment Directive 2014/53/EU (RED) **which is not under the supervision of DEKRA** and respectively with the following standards for the Radio Equipment:
- EN 300 328 V2.2.2
 - EN 301 489-1 V2.2.3
 - EN 301 489-17 V3.2.4
 - EN 62479:2010
- ③ AU mains plug/adapter.



MEGO AFEK AC Ltd.
Compression Therapy Systems

Product List B - Garments (use as accessories for devices) - (Company Prefix 729010587)

Garment description	Model	Basic UDI-DI	Product PN	Time related information	Notes
				From date	
LP12 Arm W/Shoulder S NRC-ARM	ARM	729010587ARMJS	L41111C1	2022-11-27	
LP12 Arm W/Shoulder M NRC-ARM			L41111C2	2018-06-05	
LP12 Arm W/Shoulder L NRC-ARM			L41111C3	2018-11-06	
FL Sleeve 2-75 RC-FLS	FL	729010587FLT2	L4132075	1998-06-23	
FL Sleeve 2-85 RC-FLS			L4132085	1998-06-23	
FL Sleeve 2-95 RC-FLS			L4132095	2017-12-07	
FL Sleeve 2-105 RC-FLS			L4132105	2018-01-16	
FL sleeve 3-75 RC-FLS			L4133075	2017-05-24	
FL sleeve 3-85 RC-FLS			L4133085	1998-06-23	
FL sleeve 3-95 RC-FLS			L4133095	1998-06-23	
FL sleeve 3-105 RC-FLS			L4133105	2018-06-05	
FL sleeve 4-75 RC-FLS			L4134075	1998-06-23	
FL sleeve 4-85 RC-FLS			L4134085	2017-12-07	
FL sleeve 4-95 RC-FLS			L4134095	2017-12-07	
ComfySleeve 1-75 S-Left NRC-JKT	JKTAT	729010587JKTATDF	L41LS175L	2012-12-12	
ComfySleeve 1-75 S-Right NRC-JKT			L41LS175R	2012-12-12	
ComfySleeve 1-75 M-Left NRC-JKT			L41LM175L	2012-12-12	
ComfySleeve 1-75 M-Right NRC-JKT			L41LM175R	2012-12-12	
ComfySleeve 1-75 L-Left NRC-JKT			L41LL175L	2012-12-12	
ComfySleeve 1-75 L-Right NRC-JKT			L41LL175R	2012-12-12	
Left Arm and Torso NRC-JKT			L41L0175L	2017-02-27	
Right Arm and Torso NRC-JKT			L41L0175R	2017-02-27	
Comfysleeve 2-75 NRC-LEG	COMFY	729010587COMFYBL	L41L2275	2017-02-19	
Comfysleeve 2-85 NRC-LEG			L41L2285	2007-01-28	
Comfysleeve 2-95 NRC-LEG			L41L2295	2009-01-19	
Comfysleeve 3-65 NRC-LEG			L41L2365	2007-01-28	
Comfysleeve 3-75 NRC-LEG			L41L2375	2007-01-28	
Comfysleeve 3-85 NRC-LEG			L41L2385	2007-01-28	
Comfysleeve 4-75 NRC-LEG			L41L2475	2017-01-17	
Lympha Press Pants(FB) NRC-PNT	PNT	729010587PNTM7	L4MP2130C	2019-09-24	
Lympha Press Pants(FS) NRC-PNT			L4MP2136C	2019-08-07	
Lympha Press Pants(FB-XL) NRC-PNT			L4MP2230C	2019-10-23	
Lympha Press Pants(FS-XL) NRC-PNT			L4MP2236C	2019-10-23	
LymphaPod - Left Hose NRC-POD	POD	729010587PODLA	L4MP800L	2012-12-12	
LymphaPod - Right Hose NRC-POD			L4MP800R	2012-12-12	
LymphaPod L.Hose closed NRC-POD			L4MP80BL	2022-03-22	
LymphaPod R.Hose closed NRC-POD			L4MP80BR	2022-01-17	
Lympha Jacket, Short Arm NRC-JKT	JKT	729010587JKTKY	L4MJ2125	2008-01-23	
Lympha Jacket, Long Arm NRC-JKT			L4MJ2135	2008-01-23	