

Declaration of Conformity

Manufacturer: Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.

Address: Merkez Mh. Güngören Cd. No 32/A 34200 Bağcılar/İstanbul/TÜRKİYE

Basic UDI-DI: 869878501KDZSTD6J

Product name: Manual Wheelchairs

Product Brand: Golfi

Product Type/Model:

Manual Wheelchairs: Golfi-2, Golfi-2C, Golfi-2 Eko, Golfi-3, Golfi-4, Golfi-4C, Golfi-5, Golfi-5 Banolet, Golfi-6, Golfi-7, Golfi-8, Golfi-9, Golfi-10, Golfi-11, Golfi-12, Golfi-13, Golfi-14, Golfi-15, Golfi-16, Golfi-16C, Golfi-17, Golfi-18, Golfi-19, Golfi-20, G099, G100, G100X, G100Y, G101, G100C, G103, G103Y, G105, G120, G121, G123, G124, G124C, G125, G125A, G126, G130, G131, G133, G135, G140, G301, G305, G311, G333, G400, G458, G458C, G468, G500, G501, G502, G503, G505, G506, G507, G508, G540, G541, G550, G551, G561, G605, G606, G630, G636, G637, G660

Rule and Classification: Rule I and Class I

Procedure: Annex II, Annex III and Article 19 + Annex IV

Standards: ISO 13485, EN ISO 14971, ISO 15223-1, EN 12183

We herewith declare that:

The above-mentioned products meet the requirements of Medical Device Regulation(EU) 2017/745 and the applicable standards above.

Certificate number: EC-DEC-02/02

Date of certification: 29.05.2023



Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.

General Manager: (Date & Signature)

KARADENİZ MEDİKAL SAĞLIK
HİZMETLERİ SAN.VE TİC.LTD.ŞTİ.
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NO:6 DİLOVASI/KOZLU
ULUÇINAR (D-50900) 34687
T.C.SİG. NO: 385700

Declaration of Conformity

Manufacturer: Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.

Address: Merkez Mh. Güngören Cd. No 32/A 34200 Bağcılar/İstanbul/TÜRKİYE

Basic UDI-DI: 869878501KDZAKL3D

Product name: Electrically powered wheelchairs and scooters

Product Brand: Jetty, Scuba



Product Type/Model:

Power Wheelchair: Jetty (JT-098, JT-099, JT-100, JT-101, JT-110, JT-W111A, JT-124, JT-200, JT-201, JT-220, JT-301, JT-309, JT-311, JT-320, JT-400)

Scuba (S190, S220, S250, S301)

Scooter: Scuba (S350, S400, S550)

Stair Climber: Scuba (S150)

Rule and Classification: Rule I and Class I

Procedure: Annex II, Annex III and Article 19 + Annex IV

Standards: ISO 13485, EN ISO 14971, ISO 15223-1, EN 12184, ISO 7176-21

We herewith declare that:

The above-mentioned products meet the requirements of Medical Device Regulation(EU) 2017/745 and the applicable standards above.

Certificate number: EC-DEC-03/02

Date of certification: 29.05.2023



Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.

General Manager: (Date & Signature)

KARADENİZ MEDİKAL SAĞLIK
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Declaration of Conformity

Manufacturer: Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.

Address: Merkez Mh. Güngören Cd. No:32/B 34200 Bağcılar/İstanbul/TÜRKİYE

Product name: Dual motor hospital bed

Product Brand: Azka

Product Type/Model: AZKA A1001, Reha2 Air Cushion

Rule and Classification: Rule I and Class I

Procedure: Annex II, Annex III and Article 19 + Annex IV

Standards: TS EN 60335-1:2012 + AC:2014 + A11:2014 + A13:2017

TS EN 62233:2009, TS EN 60601-1:2007(Third Edition) + Corr. 1:2006 +
Corr. 2:2007 + A1:2012 / TS EN 60601-1/A1:2014

We herewith declare that:

The above-mentioned products meet the requirements of low voltage directive (LVD) (2014/35/EU) and Medical Device Regulation(EU) 2017/745 and the applicable standards above.

Certificate number: EC-DEC-06/01

Date of certification: 29.05.2023



Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.

General Manager: (Date & Signature)

KARADENİZ MEDİKAL SAĞLIK
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Declaration of Conformity**Manufacturer:** Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.**Address:** Merkez Mh. Güngören Cd. No 32/A 34200 Bağcılar/İstanbul/TÜRKİYE**Basic UDI-DI:** 869878501KDZYRM7U**Product name:** Patient Aid Products**Product Brand:** Loco**Product Type/Model:****Walking Stick:** BS-103, BS-104, BS-105, BS-106, BS-107, PR-102, PR-103, PR-104, PR-105, PR-106, PR-107, TP-843, TP-844, TP-848**Canedian:** KN-601, KN-602, PR-601, PR-602, PR-603, PR-603C, PR-681, PR-691**Armpit Cruthes:** KA-911, KA-913, PR-900, PR-911M, PR-911L, PR-911S, PR-981, PR-981C, PR-991, PR-999**Walkers:** WR-440, WR-441, WR-443, WR-444, WR-447, PR-440, PR-441, PR-442, PR-444, PR-446, PR-447, PR-448, PR-449, PR-450, PR-491**Commode:** KT-770, KT-771, KT-773, KT-775, KT-777, PR-770, PR-771, PR-772**Rolators:** PR-881, PR-882, PR-888, PR-891, PR-441, PR-443, PR-445**Tripod:** PR-843**Quadripod:** PR-844**Rule and Classification:** Rule I and Class I**Procedure:** Annex II, Annex III and Article 19 + Annex IV**Standards:** ISO 13485, EN ISO 14971, ISO 15223-1, EN ISO 11334-1**We herewith declare that:**

The above-mentioned products meet the requirements of Medical Device Regulation(EU) 2017/745 and the applicable standards above.

Certificate number: EC-DEC-04/01**Date of certification:** 29.05.2023**Karadeniz Medikal Sağlık Hizmetleri ve Tic. Ltd. Şti.****General Manager: (Date & Signature)**

KARADENİZ MEDİKAL SAĞLIK
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