EC Declaration of Conformity

CE

issued in accordance with EC directive 93/42/EEC relating to Medical Devices

Manufacturer:	Karadeniz Medikal Sağlık Hizmetleri San Tic Ltd Şti. Merkez Mh. Gungoren Cd. No:32/B Bagcilar/Istanbul/TURKEY
Product name:	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,G100C,G103,G130,G131,G135,G120,G121,G123,G124,G124C,G124E G125,G125A,G126,G100,G100Y,G101,G105,G133,G140,G301,G305,G311,G333,G400,G458,G458C,G468, G500,G501,G507,G550,G551,G561,G502,G503,G505,G508,G605,G606,G630,G636, G637, G660,JT- 099, JT-100,JT-101,JT-W111A,JT-200,JT-201,JT-220,JT-311,JT-320, S150,S190,S200,S220,S400,S300,S550,BS-103,BS-104,BS-105,BS-106,BS-107,KN-601,KN-602, KA-911,KA-913,WR-440,WR-441,WR-443,WR-444,WR-447,KT-770,KT-771,KT-773,KT-775, KT777,TP-843,TP-844,TP-848,PR-102,PR-103,PR-104,PR-105,PR-106,PR-107,PR-440,PR-601, PR-602,PR-603,PR-603C,PR-843,PR-844,PR-440,PR-441,PR-442,PR-443,PR-444,PR-445,PR-446,PR-447,PR-448,PR-449,PR-711,PR-911,PR-770,PR-771,PR-881,PR-882,PR-888,PR-691,PR-981,PR-991,PR-999,PR-491,PR-891,REHA2
Product description:	Manual Wheelchairs, Power Wheelchairs and Patient Aid Products
Applied directives:	The Directive 93/42/EEC on medical devices, conformity assessment according to Annex VII (as a Class I non-sterile device)
Applied harmonized standards:	EN 12183, EN 14971, EN 980

The company **Karadeniz Medikal Sağlık Hizmetleri San Tic Ltd Şti.**. herewith declares that the above-mentioned product meets all applicable provisions of the Directive 93/42/EEC. The product is safe under prescribed and reasonably foreseeable conditions of storage and use.

The company has implemented measures assuring that all products of the above mentioned type are safe and fulfil essential requirements of the 93/42/EEC Directive.

The company has instituted and keeps up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means for any necessary corrective actions. The company undertakes to notify trough its Authorized Representative in EU member state the Competent Authority on any malfunction or deterioration in the product characteristics, performance or inadequacy in the instruction for use which might lead to death or serious damage of patient's health as well as on technical or medical reason leading to systematic recall of the product by manufacturer.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid in relation to the modified product.

Date of issue: 2nd February, 2022

KARADENİZ MEDİKAL SAĞLIK HİZMETLERİ SAN.VE TİC.LTD.ŞTİ.
ÇERKEŞLİ OSB MAH.İMES-7.CAD.İMES OSB NO:6 DİLOVASI KOCAELİ
ULUÇINAR VD-5090075967
TİC.SİC.NO:385700

Kemal AZAK, President
On Behalf of Karadeniz Medikal
Sag.Hiz.San. ve Tic. Ltd.Sti.