CERTIFICATE

kiwa

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-20-732

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

İDEAL MAKİNA ENDÜSTRİ ÜRÜNLERİ SAN. VE TİC. A.Ş

Esenkent mh. Nato Yolu Cd. No: 277, Ümraniye / İstanbul / Türkiye

Brand: İdeal Makina

Models: IM-GO 10 / IM-GO 20 / IM-GO 30 / IM-GO 40 / IM-GO 60 / IM-GO 100 / IM-GO 120 / IM-GO 150 / IM-GO 200 / IM-GO 300 / IM-GO 300 SE / IM-GO 300 D / IM-GO 400 / IM-GO 400 SE / IM-GO 400 D / IM-GO 600 / IM-GO 800 / IM-GO 1000 / IM-GO 1400 / IM-GO 1500 / IM-GO 2000 / IM-GO 2500 / IM-GO 3000 / IM-GO 4000

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: **M.5649.03**
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

18 December 2020, Istanbul, Turkiye

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No 15 Tepeören, Tuzla, İstanbul, Turkey
Tel.: +90 216 593 25 75 . Fax: +90 216 593 25 74
Web: www.kiwa.com.tr . e-mail: posta@kiwa.com

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EC-Declaration of Conformity, in accordance to 93/42/EC Annex II.3
Medical Devices

CE

We hereby certify that the complete machinery described in the following part is conform to all pertinent regulations of EC-Directive 2006/42/EC on machinery and fulfils the safety- and health requisitions of the EC Directives.
The machinery is moreover conform to all regulations of EC-Directive 2014/35/EU on electrical equipment and 2014/35/EU on electromagnitical compatibility and on Annex I of Pressure Equipment Directive 2014/68/EU and Annex III Part for the product vessel. The certificate number for Pressure Equipment Module B is CAC-P-0037-01 and The certificate number for Pressure Equipment Module D is CAC-P-0037-02

Manufacturer	Address	IDEAL MAKINA END. URUN. SAN. VE TIC A.S. Esenkent Mah. Nato Yolu Cad. No:277 34776 Umraniye – ISTANBUL, TURKEY
Product	Designation	Oxygen Generator
	Type / Model	IM-GO 10/20/30/40/50/60/100/120/150/190/200/ 300/300SE/300D/400/400D/600 /800/1000/1400/1500/2000/2500/3000/4000
	Class	IIa
	Year built	2022
Documentation	The technical documentation pertaining to this complete machinery according to Annex VII of EC-Directive 2006/42/EC was provided.	
Manufacturing control	Manufacturing control according to Annex VIII 2006/42/EC relies on a certified/company internal Quality Management System.	
Directive	We declare that the machinery correspond with the directive 93/42/EEC and were subjected to the conformity assessement procedure 'Internal Control of Production'	

Following harmonised standards in terms of above mentioned Directives have been applied:

Reference	EN 12100-1, EN 12100-2, EN 349, EN 953, EN 983, EN 999, EN 1037, EN 1384-1/-29, EN 13850, EN 13857, EN 14121-1, EN 61496-1, EN 60204-1, EN61000-6-2, EN61000-6-4
Reports/Decisions Risk assessment	Manufacturer acceptance protocol subsequent to performance test SQS: EC-Individual Test Certificate according to EC-Directive 93/42/EC on medical device.

Istanbul, 03.01.2022

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IDEAL MAKINA END. URUN. SAN. ve TIC. A.S.
Esenkent Mh. Nato Yolu Cad. No:277 34776 Umraniye-IST
Sarıgazi V.D. 478 093 [illegible] Tic. Sic. No: 530388
www.idealmakina.com

Alpaslan Tekin, General Manager
IDEAL MAKINA ENDUSTRI URUNLERI SAN VE TIC A.S.