



Date of issue: **February/ 27/2018**

To whom it may concern

CERTIFICATE OF AUTHORISATION:

Distributorship for **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti.** products.

This is to certify that,

ECOCHIMIE Ltd.

5/1, Cuza Voda str.

2060MD, Chisinau,

Republic of Moldova

Tel/fax +373(22)-52-34-32, 52-34-22

infoecochimie@gmail.com

info@ecochimie.md

www.ecochimie.md

is our authorized distributor for the complete **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti** product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti** products to their customers in his area and to participate in tenders on behalf of **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti**

President

Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti



Halil Demir
**DISPOSED SAĞLIK ÜRÜNLERİ ÜRETİM
SAN. VE TİC. İTH. İHR. LTD. ŞTİ.**
5748 Sok. No:69 Meriç Mh. MTK Sit. Bornova-İZMİR
Tel: +90(232) 431 22 77 (pbx) Fax: +90(232) 431 22 79
Tic Sic No: 271204 / Kıs. Sic No: 3810-5683-1100019
Eğr. VD.301 056 8311

Disposed Sağlık Ürünleri Üretim Sanayi ve Ticaret İthalat İhracat Ltd. Şti.

tel: +90(232) 431 22 77(pbx) • faks: +90(232) 431 22 79

5748 Sok. No:69 Meriç Mahallesi MTK Sitesi Bornova / İZMİR

www.disposed.com.tr • info@disposed.com.tr



Certificate of representation

This is to certify that **ECOCHIMIE S.R.L.**, Chisinau, Republic of Moldova is the certified agent in the territory of **Moldova** for equipment manufactured by **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti**, 5748 Sok No:69 MTK Sitesi Bornova/Izmir/TURKEY. This agent is authorized to act as a local representative of **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti** and to deal in all matters concerning this equipment in the aforementioned territory, when acting in capacity of representative.

This certificate has been issued and signed by President of **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti**. It is dated **02/27/2018** and it will remain valid for a period of three years from this date, at which time, it may be extended or terminated by manual agreement of **Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti** and **ECOCHIMIE**.

President

Name of Your Company Disposed Sağlık Ürünleri Üretim San. ve Tic. İth. İhr. Ltd. Sti



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ISTITUTO DI RICERCHE E COLLAUDI

M. MASINI S.r.l.

Sede amministrativa e laboratori – Head office and laboratories: Via Moscova, 11 - 20017 RHO (MI - ITALIA)
Sede Legale – Registered office: Via G. Leopardi, 14 - 20123 MILANO - ITALIA
Tel. +39.02.97071.800 - Fax +39.02.930.8176 - www.istitutomasini.it - info@istitutomasini.org

Organismo Notificato n° 0068 - Notified Body n° 0068

CERTIFICATO CE DI APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/030-2017

secondo allegato V della Direttiva 93/42/CEE sui Dispositivi Medici
e successive modifiche ed aggiornamenti
according to Annex V of Directive 93/42/EEC on Medical Devices
and its subsequent variations and updates

L'Istituto dichiara di avere effettuato l'esame del Sistema di Garanzia della Qualità della Produzione della Società più avanti menzionata seguendo i requisiti della legislazione citata cui essa è soggetta, come da allegato V della Direttiva 93/42/CEE sui Dispositivi Medici. L'Istituto certifica che il Sistema Qualità della Produzione è conforme ai requisiti essenziali della legislazione citata.

The Istituto hereby declares that an examination of the under mentioned firm production quality system has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex V of the Directive 93/42/EEC on Medical Devices. The Istituto certifies that the production quality system conforms with the relevant provisions of the aforementioned legislation.

PRATICA:
Practice

030/16/DM-CE del/of 06/12/2016

FABBRICANTE:
Manufacturer

**DISPOSED SAĞLIK ÜRÜNLERİ ÜRETİM SAN. VE TİC. İTH. İHR. LTD.ŞTİ.
MTK Sitesi 5748 sok. No:69 Meriç Mah. Bornova / İZMİR - TURKEY**

DISPOSITIVO/I:
Device/s

- Disposable surgical drapes
- Surgical Gowns
- Surgical Drape Packs
- Equipment Covers

MODELLO/I:
Model/s

see annex 1

RIF. FASC. TECNICO
Technical File ref.,

**T01
Rev 01 of 08/12/2016**

CLASSIFICAZIONE:
Classification

Is

PRIMA EMISSIONE:
First issue

07/04/2017

DOC. IN REVISIONE
Review no.

00

PRESENTE EMISSIONE:
Present issue

07/04/2017

VALIDO FINO AL:
Valid until

07/04/2020

Documenti di riferimento - Reference documents

- Delibera del Comitato Tecnico / Resolution of the Technical Committee n. VCT-DM/07/17 emesso il/issued on 07/04/2017.



Il Direttore Tecnico / The Technical Manager
Dott. Ing. Sergio Tosi

To whom it may concern

CONFIRMATION

We confirm that Disposed sağlık ürünleri has been audited for compliance with the Medical Device Directive and is in the process of evaluating the implementation and effectiveness of the corrective actions for granting the certification. Additional time is required for the follow up assessment due to the coronavirus epidemic.

Nicosia, 03/04/2020



Filippos Kottis
Certification Director



HTCert

HTCert is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification Number 2803



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Organismo Notificato n° 0068 - Notified Body n° 0068

ALLEGATO N. 1 AL CERTIFICATO CE DI APPROVAZIONE DEL SISTEMA DI GARANZIA DELLA QUALITÀ DELLA PRODUZIONE PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/030-2017

secondo allegato V della Direttiva 93/42/CEE sui Dispositivi Medici
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Il presente allegato è da considerare riferito ai seguenti prodotti:

This annex covers the following devices

Product description

General Surgery Drape Pack	Lithotomy Drape Pack	Adhesive Drape	Cesarean Drape
Laparoscopy Drape Pack	Ophthalmic Drape Pack	Reinforced Adhesive Drape	Laparoscopy Drape
By-pass Drape Pack	Cataract Drape Pack	Back Table Cover	OPU Drape
Valve Replacement Drape Pack	Embryo Transfer Drape Pack	Minor Fenestrated Drape	Leg Drape
Angiography Drape Pack	Laparotomy Drape Pack	Hip Drape (U Split Drape)	Towel
Craniotomy Drape Pack	ENT Drape Pack	Mayo Stand Cover	Standard Surgical Gown
Arthroscopy Drape Pack	OPU Drape pack	Ophthalmic Drape	Reinforced Surgical Gown
Extremity Drape Pack	Vertebra Drape Pack	Angiography Drape	Full Reinforced Surgical Gown
Orthopedics Drape Pack	Biopsy Drape Pack	Gynecological Drape	Fluoroscopy Cover
Hip Drape Pack	TESE Drape Pack	Extremity Drape	Cassette Cover
Tur Drape Pack	Torax Drape Pack	Craniotomy Drape	Diathermy Bag
Cystoscopy Drape Pack	Shoulder Arthroscopy Drape Pack	Arthroscopy Drape	
Percutaneous Drape Pack	Hand&Foot Drape Pack	By-pass Drape	
Cesarean Drape Pack	Dental Implant Surgery Drape Pack	Biopsy Drape	
Delivery Pack	Epidural Drape Pack	Embryo Transfer Drape	
Gynecological Drape pack	Plain Drape	T.U.R Drape	



CERTIFICATE of Registration



*This is to Certify that the
Medical Devices – Quality Management System
of*

DİSPOSED SAĞLIK ÜRÜNLERİ ÜRETİM SANAYİ VE TİCARET İTHALAT İHRACAT LİMİTED ŞİRKETİ

**MTK SİTESİ MERİÇ MAH. 5748 SOK. NO:69
BORNOVA / İZMİR / TÜRKİYE**

**has been independently assessed and is compliant
with the requirements of**

ISO 13485:2016

**This Certificate is applicable to the following product or service ranges:
PRODUCTION AND SALES OF DISPOSABLE SURGICAL DRAPES, APRONS,
DEVICE COVERS AND COVER SETS**

**TEK KULLANIMLIK CERRAHİ ÖRTÜLER, ÖNLÜKLER, CİHAZ KILIFLARI
VE ÖRTÜ SETLERİNİN ÜRETİMİ VE SATIŞI**

:: Certificate No :: TR51111H

Date of initial registration	10 June 2019
Date of this Certificate	10 June 2019
Surveillance audit on or before	09 June 2020
Recertification Due / Certificate expiry	09 June 2022

**This Certificate is property of Staunchly Management & System Services Pvt. Ltd. and remains valid
subject to satisfactory surveillance audits.**



Director

**STAUNCHLY MANAGEMENT & SYSTEM SERVICES LIMITED
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN**



ACCREDITED
Management Systems
Certification Body
MSCB-125

Phone: +44 345 680 0199 | Email: info@staunchlyservices.com | Web: www.staunchlyservices.com

For precise and updated information concerning the present certificate mail to info@staunchlyservices.com

This Certificate is the property of Staunchly Management & System Services Pvt. Ltd. and shall be returned immediately when demanded.

SMS/F109A/17/REV