



2024

FDA COSMETICS DIRECT

COSMETIC FACILITY REGISTRATION

Document Type: Cosmetic Facility Registration

Version Number: 1

Effective Date: 25.06.2024

REGISTRATION DETAILS:

Facility Name: Elit Pharma Kozmetik ve Ilac San.Tic. Ltd.Sti

Facility FEI Number: 3016195849

Parent Company Name: Elit Biotech GmbH

Facility Country: Turkey

Facility Street Address: Karayollari Mah.Cebeci Cad No:204 34255,Gaziosmanpasa Istanbul Turkiye

FACILITY BRAND NAMES: Cliniclub,Hairmd,Dermobella,Dentalab,We Made Pro

RESPONSIBLE PERSON NAME: Elit Pharma Kozmetik ve Ilac San.Ltd.Sti,
EU Responsible Elit Biotech GmbH

PRODUCT CATEGORY CODES:

- (06) Hair preparations (non-coloring)- (A) Hair conditioners- 1. Leave-on
- (06) Hair preparations (non-coloring)- (A) Hair conditioners- 2. Rinse-off
- (06) Hair preparations (non-coloring)- (C) Hair straighteners
- (06) Hair preparations (non-coloring)- (F) Shampoos (non-coloring)- 2. Rinse-off
- (06) Hair preparations (non-coloring)- (I) Other hair preparations- 1. Leave-on
- (06) Hair preparations (non-coloring)- (I) Other hair preparations- 2. Rinse-off
- (11) Oral products- (B) Mouthwashes and breath fresheners (liquids and sprays)
- (12) Personal cleanliness- (A) Bath soaps and body washes
- (12) Personal cleanliness- (F) Other personal cleanliness products- 2. Rinse-off
- (14) Skin care preparations (creams, lotions, powder, and sprays)- (A) Cleansing (cold creams, cleansing lotions, liquids, and pads)
- (14) Skin care preparations (creams, lotions, powder, and sprays)- (F) Moisturizing
- (14) Skin care preparations (creams, lotions, powder, and sprays)- (G) Night
- (14) Skin care preparations (creams, lotions, powder, and sprays)- (I) Skin fresheners
- (14) Skin care preparations (creams, lotions, powder, and sprays)- (J) Other skin care preparations- 1. Leave-on
- (14) Skin care preparations (creams, lotions, powder, and sprays)- (J) Other skin care preparations- 2. Rinse-off

CONFIRMATION STATEMENT: Your submission has gone through the FDA validation process.

Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

Facility Registration: Manufacturers and processors must register their facilities with FDA and renew their registration every two years.

- FDA has the authority to suspend a facility's registration if the agency determines that a cosmetic product manufactured or processed by the registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans, and the agency has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility. If a facility's registration is suspended, it is a prohibited act to distribute or sell (or otherwise introduce or deliver into commerce) in the United States cosmetic products from the facility.

We declare hereby that Elit Pharma Kozmetik ve İlaç San.Tic.Ltd Sti. has facility registration approval with FDA Cosmetics Direct.



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