



DEPARTMENT OF THE TREASURY
WASHINGTON, D.C.

OFFICE OF FOREIGN ASSETS CONTROL

Western Balkans Stabilization Regulations
31 CFR part 588

GENERAL LICENSE NO. 3

**Authorizing Certain Transactions Related to Agricultural Commodities,
Medicine, Medical Devices, Replacement Parts and Components, Software Updates, or
Medical Prevention, Diagnosis, or Treatment, or Clinical Trials Involving
Orka Holding AD**

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by the Western Balkans Stabilization Regulations (WBSR), 31 CFR part 588, involving Orka Holding AD, or any entity in which Orka Holding AD owns, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest, related to the following are authorized: (1) the production, manufacturing, sale, transport, or provision of agricultural commodities, agricultural equipment, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices; (2) the prevention, diagnosis, or treatment of any disease or medical condition; or (3) the conducting of clinical trials or other medical research.

(b) For the purposes of this general license, agricultural commodities, medicine, and medical devices are defined as follows:

(1) Agricultural commodities. Agricultural commodities are products that fall within the term “agricultural commodity” as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602) and are intended for use as:

(i) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(ii) Seeds for food crops;

(iii) Fertilizers or organic fertilizers; or

(iv) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) Medicine. Medicine is an item that falls within the definition of the term “drug” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) Medical devices. A medical device is an item that falls within the definition of “device” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(c) This general license does not authorize any transactions otherwise prohibited by the WBSR, including transactions involving any person blocked pursuant to the WBSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Note to General License No. 3. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies.

Bradley T. Smith Digitally signed by Bradley T. Smith
Date: 2023.11.16 07:41:08 -05'00'

Bradley T. Smith
Director
Office of Foreign Assets Control

Dated: November 16, 2023