



## Office of Foreign Assets Control

### 31 CFR Part 510

## Publication of the List of Medical Devices Requiring Specific Authorization for the North Korea Sanctions Regulations

**AGENCY:** Office of Foreign Assets Control, Treasury.

**ACTION:** List of medical devices excluded from North Korea Sanctions Regulations general license.

**SUMMARY:** The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing a list of medical devices that may not be exported or reexported to North Korea pursuant to the general license authorizing the exportation or reexportation to North Korea of certain agricultural commodities, medicine, medical devices, and replacement parts and components. The exportation or re-exportation of these excluded medical devices to North Korea requires specific authorization from OFAC.

**DATES:** This list is effective [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** OFAC: Assistant Director for Regulatory Affairs, 202-622-4855; or <https://ofac.treasury.gov/contact-ofac>.

### SUPPLEMENTARY INFORMATION:

#### Electronic Availability

This document and additional information concerning OFAC is available on OFAC's website (<https://ofac.treasury.gov>).

#### Background

On February 16, 2024, OFAC adopted a final rule (89 FR 12233) amending the North Korea Sanctions Regulations, 31 CFR part 510 (the "Regulations"), to, among other things, add a new general license at § 510.521 authorizing the exportation or

reexportation to North Korea of certain agricultural commodities, medicine, medical devices, and replacement parts and components that are not subject to the Export Administration Regulations, 15 CFR parts 730 through 774. Section 510.521(b)(3) defines a medical device to mean an item that (i) falls within the definition of “device” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), and (ii) is not on the List of Medical Devices Requiring Specific Authorization (the “List”), as maintained on OFAC’s website (<https://ofac.treasury.gov>) on the North Korea Sanctions page. OFAC is now publishing the List in the *Federal Register* and on its website.

The text of the List is provided below.

**List of Medical Devices Requiring Specific Authorization ([INSERT DATE OF PUBLICATION IN FEDERAL REGISTER])**

**The list below comprises the List of Medical Devices Requiring Specific Authorization as identified in 31 CFR 510.521(b)(3)(ii)**

General Medical Supplies and Equipment

- Oxygen Generators
- Pumps with flow rates of more than 1 liter/minute
- Diagnostic Medical Imaging Equipment:
  - Gamma imaging equipment
  - Tactile Imaging equipment
  - Thermography equipment

Laboratory

- Freeze-drying (lyophilizers) and spray-drying equipment
- Fermenters, bioreactors, and chemostats
- Crossflow (tangential) filtration systems and disposable filter cartridges
- Biocontainment chambers and hoods, including isolators, biological safety cabinets, and laminar flow hoods
- Aerosol inhalation equipment, including full-body, head-only, nose-only, and mask exposure systems
- Decontamination showers
- Laboratory glassware made from borosilicate glass, including reaction vessels, storage tanks, heat exchangers, and distillation and absorption columns
- Autoclaves larger than 20 liters
- Clinical laboratory water baths larger than 10 liters
- Laboratory hot plates exceeding 1 square foot of heating surface
- Freezers capable of reaching temperatures of -80 degrees Celsius
- Laboratory shakers and incubator shakers
- Carbon dioxide incubators

- Circular dichroism spectrometers
- Spectrometers and spectrophotometers not designed for clinical use
- Fluorometers
- Nuclear Magnetic Resonance Spectrometers
- Polymerase Chain Reaction (PCR) machines
- Differential Scanning Calorimeters
- Chromatography Equipment
- Fluorescence Microscopes
- Confocal Microscopes
- Cascade Impactors
- Dynamic Light Scattering Equipment
- Quasielectric Light Scattering Equipment
- Full face mask respirators, including Powered Air Purifying Respirators (PAPR)
- Decontamination systems using the following chemicals:
  - Vaporized hydrogen peroxide
  - Vaporized paraformaldehyde
  - Vaporized ethylene oxide
  - Isopropanol (99% purity)
- High Efficiency Particulate Air (HEPA) Filtration Systems and HEPA filters
- Fourier Transformation Infrared (FTIR) Systems
- Balancing machines
- Motion simulators
- Rate tables
- Fluorescence-activated cell sorters (FACS)

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BILLING CODE 04810-AL

[FR Doc. 2026-11761 Filed: 6/10/2026 8:45 am; Publication Date: 6/11/2026]