



## Chemfort® is FDA cleared under ONB product code

### **Chemfort® is a leading closed system transfer device (CSTD), designed to meet the highest safety standards when handling hazardous drugs**

Chemfort® is intended for the preparation, compounding and administration of antineoplastic and other hazardous drugs, keeping pharmacists, nurses and other health care workers safe.

Chemfort® introduces new design and raw material upgrades, delivering a new level of efficiency, performance and ease of use, and has no known incompatibilities with hazardous drug solvents.

The Food and Drug Administration (FDA or USFDA) is a federal agency of the United States Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices and others.

## CSTD GUIDELINES

### What does ONB clearance mean?

It means that the FDA has found that Chemfort® meets the standard for closed system transfer devices.

### What is unique about Chemfort® compared to other ONB devices?

Chemfort® has the patented drug binding mechanical barrier ToxiGuard® technology, which prevents airborne contaminants from entering the drug vial (locks out), as well as the escape of hazardous drug vapors, aerosols or droplets to the

environment (locks in). The ToxiGuard® technology enables automatic equalization of pressure within the drug vial as diluent is added or drug is withdrawn, and retains sterility of the drug vials even after multiple uses.

### What is the significance of the FDA ONB Product Code?

Prior to establishment of the ONB product code, Closed System Drug Transfer Devices such as Chemfort® were evaluated by the FDA under the General Hospital Devices Branch (GHDB). The ONB product code established a new standard for the industry that is specific for Closed System Drug Transfer Devices. The ONB product code is a part of the regulation description for Intravascular

Administration sets, but it is specific for CSTDs. ONB clearance is attained following presentation of data and tests which verify that the device prevents the escape of fluids, droplets and aerosols and in parallel prevents entry of microbial and airborne contaminants to the fluid path /drug.

### How does the FDA define the ONB Product Code?<sup>1</sup>

In 2012, the U.S. Food and Drug Administration (FDA) began issuing 510(k) clearances under the product code ONB. All devices that are FDA cleared under the ONB code are considered as CSTDs **regardless** of their technology (drug-binding mechanical barrier, membrane-only, or physical barrier).

#### Device

Closed Antineoplastic and Hazardous Drug Reconstitution and Transfer System

#### Regulation Description

Intravascular Administration Set

#### Definition

Reconstitute and transfer antineoplastic and other hazardous drugs in healthcare setting indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare settings

#### Physical State

According to the FDA, the ONB product code is applicable for devices that have the ability to reconstitute and transfer antineoplastic and other hazardous drugs indicated to reduce exposure of healthcare personnel to chemotherapy agents in healthcare settings.

### Indications for Use

Chemfort® is a Closed System Transfer Device (CSTD) that mechanically prohibits the release of drugs, including antineoplastic and hazardous drugs, in vapor, aerosol, or liquid form during preparation, reconstitution, compounding

and administration, minimizing exposure of individuals, healthcare personnel and the environment to hazardous drugs. Chemfort® prevents the introduction of microbial and airborne contaminants into the drug or fluid path for up to 7 days.

1. FDA site: <https://www.fda.gov/default.htm>

