

**TWINBIRD : Japan's first ever <sup>(※1)</sup> for WHO medical equipment quality certification**

**TWINBIRD has been certified to WHO (World Health Organization) PQS (medical equipment quality certification).**

**The very first in Japan in the relevant category <sup>(※1)</sup>,  
third in Japan in all categories <sup>(※2)</sup>  
SC-DF25P Deep Freezer P (Country of origin: Japan)**

TWINBIRD Corporation (CEO: Nomizu Shigeaki, Head Office: Tsubame City, Niigata Prefecture) has been certified to the World Health Organization (WHO) medical equipment quality certification (Performance, Quality and Safety, PQS) in October 2024 for its freezer used to store vaccines at the appropriate temperature. The SC-DF25P (product name: Deep Freezer P) is listed in the WHO PQS catalog and will serve as the standard for selecting medical equipment in various countries in the future. PQS certification category: E003. This is the first vaccine freezer/refrigerator in Japan and the third across all categories.



SC-DF25P

## Background

Vaccines play an important role not only in preventing infectious diseases and serious illness, but also in herd immunity. According to UNICEF's flagship report, "The State of the World's Children 2023," the number of deaths of children under the age of five worldwide has dropped remarkably from 12.5 million per year in 1990 to 5 million in 2021 thanks to vaccines. While further improvement is expected as vaccines become more widely available around the world, many developing countries still face the challenges such as facilities for freezing and refrigerating and a transportation system in order to smoothly implement vaccinations.

In order to contribute to the SDGs' "Ensure healthy lives and promote well-being for all at all ages," TWINBIRD has been preparing since 2021 to obtain WHO PQS certification in order to promote efforts to solve global social issues using freezers equipped with TWINBIRD's proprietary cooling technology, FPSC (Free Piston Stirling Cooler) refrigeration units. There were two major achievements that led to the application.

(※1) As of October 2024, in the PQS certification category: "E003 Vaccine Freezers and Vaccine Refrigerators"  
(※2) As of October 2024, across all categories

① Supplying vaccine freezers in Japan

In 2021, we delivered approximately 12,000 SC-DF25WL (product name: Deep Freezer 25L, a similar model to the SC-DF25P) units, which can transport vaccines at a low and constant temperature to prevent COVID-19 to “the Ministry of Health, Labor and Welfare” and “Takeda Pharmaceutical Co., Ltd”. The products have been used mainly by local governments and companies across the country for workplace vaccinations, leading to their credibility.

② Providing vaccine storage to developing countries

Participating in the “Last One Mile Support” initiative run by the Ministry of Foreign Affairs and the Japan International Cooperation Agency (JICA). Starting with shipments to Timor-Leste, we have sent products to Mozambique, Senegal, Mongolia, and Palestine.



Photo: courtesy of JICA  
SC-BV25 : Cold portable type

Based on these achievements, we would like to contribute, through international organizations such as JICA and WHO, to building cold chains in regions such as Asia and Africa where vaccination is lagging behind.

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## What is WHO PQS?

WHO Performance, Quality and Safety (PQS) certification is a system for medical equipment approved by WHO. Medical equipment that has acquired PQS certification serves as the selection standard for equipment supported by UN-related organizations such as UNICEF and GAVI (※3), as well as major NGOs and charitable organizations, and plays an important role as it is mainly used in developing countries.

Only after acquiring ISO standards (ISO9001: quality management system standard ,and ISO14001: environmental management system standard) and IEC (European product safety standard) , they managed to apply for PQS, and were finally certified after testing in an accredited testing laboratory in Singapore.

This project was adopted as a subsidized project by the Ministry of Health, Labor and Welfare (WHO pre-certification and recommendation acquisition and promotion project for listing in the WHO recommended equipment directory for developing countries), with the aim of contributing to the improvement of medical standards in developing countries and promoting the international expansion of high-quality Japanese pharmaceuticals and medical equipment.

(※3)GAVI: The Global Alliance for Vaccines and Immunization is an alliance that aims to improve children’s health through vaccination programs. Its members include governments of developed and developing countries, international organizations, international NGOs, research institutes, and vaccine-related companies.

## Advantages of FPSC (Free Piston Stirling Cooler) Technology

Stirling cooler, a unique cooling technology, has the advantage of being small and having a high cooling capacity compared to compressors of the same size in temperature ranges of -30°C to -40°C and below -80°C.

### 1. Precise temperature control

Compared to conventional cooling methods using compressors, etc., temperatures can be controlled to within a degree, even at extremely low temperatures.

### 2. Application to extremely low temperatures

Cooling down to extremely low temperatures is possible.

### 3. Compact and portable

It is small, resistant to vibration, and easy to carry.

### 4. Environmentally friendly

It uses helium gas as a refrigerant, and is an eco-friendly technology because it saves energy and generates little heat.

### 5. Use in Space : High technical capabilities and reliability

These advantages have been highly evaluated, and it is still in use on the International Space Station. This is proof of its high technical capabilities and reliability.

Although the Stirling cooler is said to have a "simple structure", one of the reasons it is difficult to realize is the high level of precision required.

It is made up of around 150 parts, with the gap between the cylinders and pistons in the engine, which is its core, being just 0.01mm. This requires "10 times the precision of an automobile engine." This technology could only be realized in the Tsubame-Sanjo region of Niigata Prefecture, one of the world's leading metalworking towns, where technology has been accumulated.



## Future developments

Through the business, TWINBIRD is committed to contributing to the health of people around the world and to the creation of a sustainable society.

Currently, in the FPSC business, we are developing demand mainly in Japan, North America, and Europe in the four fields of "Pharmaceuticals/Bio," "Chemicals/Energy," "Measurement/Environment," and "Food/Distribution." We will particularly focus on the pharmaceutical/bio field, which is expanding at an annual rate of 9.6% (※4). For the transportation and storage of biopharmaceuticals, it is essential to build a cold chain with strict temperature control (freezing -20°C to -40°C, deep freezing -70°C to -85°C). We are strengthening our marketing activities to participate in the biopharmaceutical cold chain, and in addition to vaccines (preventive drugs). We are promoting business expansion into the global pharmaceutical cold chain market for biological therapeutic drugs (antibody drugs, cell therapy drugs, gene therapy drugs, etc.), which are expected to grow in the future.

As for overseas expansion, through the achievement of obtaining PQS certification, the company will strengthen our overseas activities for vaccine transport warehouses by meeting the equipment selection standards of UN-related organizations such as UNICEF, as well as major NGOs and charitable organizations.

In accordance with VISION 2030, which states, "What the FPSC business should aim to achieve: Contribute to the health of people around the world and create a sustainable society!"; we will contribute to the health of people around the world and create a sustainable society in the growing global cold chain market, based on the high reliability of Stirling refrigerators, which have been proven in COVID-19 vaccine transport facilities.

(※4)Reference: Evaluate Pharma, Worldwide Prescription Drug & OTC Sales by Technology (2012-2026)

## Initiatives toward SDGs

**To be the standard for global cold chains.**

As the company name expresses our desire to fly together as "a pair of birds" with customers, and that the joy of those who use TWINBIRD products is of our motivation, TWINBIRD hopes to deepen ties with stakeholders through the business and contribute to a more prosperous society and ultimately the realization of the SDGs. To achieve one of the SDGs, "Ensure healthy lives and promote well-being for all at all ages", we will use domestic and international networks to participate in the construction of cold chains based on the latest technology on a global scale and the expansion of medical services, and will work to make Stirling cooling technology one of the standards in the medical field.

SDGs goals that may be related through this initiative:

- Suitable for transporting vaccines and other pharmaceuticals, contributing to the advancement of medical care
- Uses helium gas, which has a zero global warming potential, as a refrigerant, reducing environmental impact
- Product development utilizing local Tsubame-Sanjo technology and artisan network



**SUSTAINABLE DEVELOPMENT GOALS**

We support the Sustainable Development Goals (SDGs)

## Specification



Product name: Deep Freezer P

Product number: SC-DF25P

Country of origin: Japan

PQS certification number: E003/141

Product category: Vaccine Freezer

Reference price: US\$ 2,500

### Accessories:

Temperature logger, temperature logger data cable, AC adapter, AC power cord, key, inner lid, mat, instruction manual

External dimensions of product: 695mm (W) x 350mm (D) x 460mm (H)

Capacity (vaccine storage capacity): 15L

Product weight: Approximately 16.5kg (product only)

Power consumption (when temperature inside the cabinet is stable): 1.01kWh/24h

Refrigerant: Helium gas

Climate classification: Hot-zone, tropical

Maximum operating temperature: +43°C

Minimum operating temperature: +0°C

Temperature retention time: 78min



## Tsubame-Sanjo, a land of craftsmanship

Tsubame-Sanjo (Tsubame City and Sanjo City, Niigata Prefecture) is known for its metal processing technology and is one of Japan's leading manufacturing towns. We aim to create products that enhance excitement and comfort by working with Tsubame-Sanjo craftsmen who keep up with the changing times and continue to meet new needs.

### <Contact>

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