

Company:	CYBERDYNE Inc.
Name of Representative:	Yoshiyuki Sankai, President and CEO
Code:	7779 (Mothers Section of the Tokyo Stock Exchange)
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### **HAL Single Joint Type obtained certification as a medical device for Japan, applied for insurance coverage**

CYBERDYNE Inc. [Tsukuba, Ibaraki, CEO: Yoshiyuki Sankai (the “Company”)] obtained certification as a medical device for Japan from a third-party certifier, for HAL Single Joint Type (HAL for Medical Use Single Joint Type, the “Product”) on July 8, 2020. Following the event, the Company applied for public health insurance coverage on July 10, 2020. The Product is designed for training of patients whose motor function of the upper and lower limbs has decreased due to muscle weakness or paralysis. The Company will start accepting orders for the Product on July 15, 2020 and commence installation once the Product gets covered by public health insurance



\*The Product is a medical device only to be operated by medical professionals. It cannot be purchased by individual users

#### **【Outline】**

Brand name: HAL for Medical Use Single Joint Type

Generic name: Active elongation/bending/elongation rotation device

Certified date: July 8, 2020

Certified number: 302AIBZX00017000

Intended use: Maintaining, developing, and recovering the muscle strength of patients whose motor functions in the upper and lower limbs have deteriorated due to muscle weakness or paralysis.

HAL for Medical Use Single Joint Type is a product that provides intensive rehabilitation of each joints by combining the main unit with the attachment suitable for various joints such as elbow and knee. Using the Product, operator could perform rehabilitation in various positions, such as lying, sitting and standing in accordance to physical conditions of the patient. The compact design of the Product makes it easy to carry around, enabling rehabilitation in a wide range of environment, such as general ward rehabilitation room and bedside room in the acute phases.

Prior to obtaining the medical device certification in Japan, HAL for Medical Use Single Joint Type was used in hospitals as a non-medical product to promote independence from care, only for the purpose of clinical research. With the acquisition of the medical device certification, medical institutions will be able to adopt the Product as a medical device for the purpose of maintaining, developing, and recovering the muscle strength of patients whose motor functions in the upper and lower limbs have deteriorated due to muscle weakness or paralysis.

The Company submitted an application for the Product to the Ministry of Health, Labour and Welfare under the category of “equipment for increasing exercise load” newly established in the “H0003-2 Comprehensive Rehabilitation Plan Evaluation Fee” based on the medical fee revision of fiscal year 2020. If the Company succeeds on obtaining insurance coverage under the aforementioned category, 150 points can be added to prescribed points as an addition of equipment for increasing exercise load with the limit of once a month, when medical institution use HAL for Medical Use Single Joint Type for rehabilitation of cerebrovascular disease etc.

Following the event, the Company will start sales activities to expand the coverage to medical institutions in Japan. Outside Japan, The Company have already obtained certification as a medical device in EU and will continue to proceed with similar regulatory process in the U.S. and Asia Pacific Region.

The Company utilized the results of research and development conducted at the “Fukushima Medical Welfare Equipment Development Grant (primary)” by Fukushima Prefecture for obtaining medical device certification on this occasion.



Elbow joint attachment



Knee joint attachment

**CYBERDYNE Inc.**

URL	<a href="https://www.cyberdyne.jp/english/">https://www.cyberdyne.jp/english/</a>
Founded	June 2004
Share capital	26.778 billion Japanese yen (as of March 31, 2020 : non-consolidated, Japanese GAAP)
CEO	President and CEO Yoshiyuki Sankai
Address	2-2-1 Gakuen-minami, Tsukuba, Ibaraki, Japan

The Group's business is to realize "Society 5.0/5.1", a future society based on the idea of Techno-Peer-Support where human and technology live together and support each other. This goal is attained through revolutionary changes in industry and society, and The Group seeks to utilize "Cybernetics Technology" (fusion and combination of systems of human, robot and information) that handles "human" + Cyberspace" + "Physical space", to create a "Cybernetics Industry" for this transition following the breakthroughs of the Robotics Industry and IT Industry.