

NEWS RELEASE

November 21, 2022

Otsuka Medical Devices certified to ISO 13485*Applied to the design, development, manufacture, distribution, and shipping of vascular stents*

Otsuka Medical Devices Co., Ltd. (“Otsuka Medical Devices,” subsidiary of Otsuka Holdings Co., Ltd.) is pleased to announce we have been certified to ISO 13485^{*1}, the international quality management system standard for medical devices. We received the certification from BSI^{*2} Group Japan K.K. in September 2022 for the design, development, manufacture, distribution, and shipping of vascular stents.

ISO 13485 certification proves that organizations in the medical device industry have established and maintained a consistent quality management system.

We will continue to enhance our efforts to maintain our quality control in design, development, manufacturing, sales, and shipping to deliver products to meet the needs of patients and medical professionals for safety and reliability.



MD 770118 / ISO 13485

Certification Overview

Applicable Certification Standard: ISO 13485:2016

Certificate Number: MD 770118

Scope of Certification:

Design, development, manufacture, distribution and shipping of vascular stent

Location Where Certified:

Otsuka Medical Devices Co., Ltd.

- Head office (2-9, Kanda-Tsukasamachi, Chiyoda-ku, Tokyo)
- Tokyo Headquarters (Shinagawa Grand Central Tower 2-16-4, Konan, Minato-ku, Tokyo)
- HARUMI Technology Center (CROSS DOCK HARUMI 4-7-4, Harumi, Chuo-ku, Tokyo)

Certification Body: BSI Group Japan K.K. (BSI Assurance UK Limited)

Original Registration Date: 2022.09.30

Expiry Date: 2025.09.29

*1 ISO 13485:2016

The ISO is an international standard for quality management systems (QMS) for the medical device industry. This QMS standard is derived from ISO 9001 and aims to maintain the safety and quality of medical devices with a focus on compliance with regulatory requirements.

*2 BSI (British Standards Institution)

Since its establishment in 1901, BSI has been the world's first national standards institute, providing standards development, assessment, and certification. BSI Group Japan is the Japanese subsidiary of BSI, established in 1999, and has conducted a large number of certifications in Japan.

About Otsuka Medical Devices Co., Ltd.

Otsuka Medical Devices Co., Ltd. focuses on the global development and commercialization of medical care products including endovascular devices that provide new therapeutic options in areas where patient needs cannot be met through pharmaceutical or other conventional treatment. Otsuka Medical Devices is a subsidiary of Otsuka Holdings Co., Ltd. (www.otsuka.com/en), a global healthcare company listed on the Tokyo Stock Exchange (JP 4578).

<https://www.omd.otsuka.com/en/>

Media contact:

OMD-PR@otsuka.jp