

Acquisition of certification for a quality management system for medical devices

"EN ISO 13485:2016"

QD Laser, Inc. (Headquarters: Kawasaki, Kanagawa, Japan, President & CEO: Mitsuru Sugawara) announces that a quality management system for medical devices of "EN ISO 13485:2016" was certified in October.


【Certified overview】

Applicable standard	EN ISO13485:2016
ID	0000071906
Effective date	2019-10-28
Scope of registration	Design and Development, Manufacture and Distribution for Medical Eyewear Using Laser Retinal Scanning
Certification body	TÜV Rheinland LGA Products GmbH

QD Laser, Inc.

QD Laser, Inc. (Headquarters: Kawasaki, Kanagawa, Japan, President & CEO: Mitsuru Sugawara) was established as a spin-off venture from Fujitsu Ltd. (Head office: Minato-ku, Tokyo; President: Takahito Tokita; hereinafter, Fujitsu) in April 2006, with the investment of Fujitsu and Mitsui & Co. Global Investment (former MVC) under Mitsui & Co., Ltd. (Head office: Chiyoda-ku, Tokyo; President: Tatsuo Yasunaga). Based on the joint development of Fujitsu Laboratories Ltd. (Head office: Kawasaki City, Kanagawa Prefecture, President: Hirotaka Hara) and the University of Tokyo by over 10 years of industry-academia collaboration, QD Laser develops, manufactures and sells high-performance semiconductor lasers including quantum dot lasers from visible to 1300 nm in wavelength. The corporate statement "Illuminating human possibilities" symbolizes our will to contribute to society through laser and optical technologies.

We have continued development of for retinal scanning laser eyewear technology including a support for a clean device society implementation promotion project by the National Research and Development Corporation New Energy and Industrial Technology Development Organization (NEDO), and a support tool for practical application

of welfare tool for FY2015. In 2018, we launched the world's first sales of RETISSA® Display, a consumer retina scanning laser eyewear.

The products which are subject to EN ISO 13485 are medical devices with built-in cameras. The release date of the models with built-in cameras is not decided. The “RETISSA® Display” and “RETISSA® Display II” retinal scanning laser eyewear products that are currently announced are products for consumer use and are not medical devices with built-in cameras.

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