



# DAICEL CORPORATION

May 13, 2022

DAICEL Corporation

## DAICEL Harima Plant obtains ISO13485:2016 Quality Management System Certification for Medical Devices

DAICEL Corporation (Head Office: Kita-ku, Osaka City, President and Chief Executive Officer: Yoshimi Ogawa, henceforth referred to as "DAICEL") has obtained ISO13485:2016 certification, the international quality management system for medical devices, at the Harima Plant, which is the manufacturing base of the automotive safety business, and Innovation Park, which is the research institute. The Harima Plant and Innovation Park are currently designing, developing and manufacturing the Novel Drug Delivery Device "Actranza™ lab.", for animal testing. Recently we have been discussing business collaboration not only with Japanese, but with European and American pharmaceutical companies, and believe obtaining ISO13485:2016 certification accelerates the overseas expansion of this business.. Taking this opportunity, we will pursue further improvements of quality control.

### <Authentication overview>

Quality Management System : ISO 13485:2016

Holds Certificate number : MD 759371

Registration date : April 14th, 2022

Registered Activity : Design and development of gas-powered needleless medication and/or vaccine injector

Location :

DAICEL CORPORATION HARIMA PLANT (805, Umaba, Ibogawa-cho, Tatsuno-shi, Hyogo)  
DAICEL CORPORATION INNOVATION PARK (1239, Shinzaike, Aboshi-ku, Himeji-shi, Hyogo)

Certification body : BSI Assurance UK Limited

### <Overview of the drug delivery device Actranza™ lab>

This technology distributes a liquid into a specific organ with a needle-free system by using a force generated from an energy control technology called "One Time Energy™ DAISI". According to the results of animal studies, a higher gene expression is achieved upon accurate delivery to skin (the dermis/epidermis layer) than with conventional needle injection. Since dermal/epidermal tissue contains more immunocompetent cells than muscle tissue, the efficacy of the vaccines can be enhanced when a vaccine is delivered by this method.

\* About "Actranza™ Lab": [https://www.daicel.com/safety/daisi/actranza\\_pr/](https://www.daicel.com/safety/daisi/actranza_pr/)



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\* About One Time Energy™ DAISI: <https://www.daicel.com/safety/daisi/>

## About Daicel

DAICEL is a diversified chemical company with business operations in Japan and around the world. Under the basic philosophy of "the company making lives better by co-creating value", Daicel provides materials that benefit society and people in a wide range of business fields with the keywords of "health," "safety and security," "convenience and comfort," and "environment".

Through our Mid-term Management strategy, we will focus on the creation of new biomass product trees using renewable resources such as forest resources and the development of innovative process technologies to realize them in an environmentally friendly manner, utilizing the plant-derived cellulose technology that we have been dealing with since our establishment, to create a recycling-oriented society that leads to carbon neutrality. For more information about Daicel, please visit <https://www.daicel.com/en/>.