CERTIFICATE

Number: 49289

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Ophtec B.V.

Schweitzerlaan 15 9728 NR Groningen The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

The design, development, manufacture and distribution of medical devices for the area of ophthalmology, including purchase and resale of ophthalmic devices and accessories for ophthalmological applications.

Certificate expiry date: 1 July 2024
Certificate effective date: 1 July 2021
Certified since: 1 May 2001

This certificate is valid for the organization(s) and/or locations/mentioned on/the addendum.

DEKRA Certification B.V.

B.T.M. Holtus Managing Director J.A. van Vugt Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 49289

The management system of the organization(s) and/or location(s) of:

Ophtec B.V.

Schweitzerlaan 15 9728 NR Groningen The Netherlands

Certified organization(s) and/or locations:

Different scope

Ophtec B.V. Schweitzerlaan 11 9728 NR Groningen Design and development and marketing of medical devices for the area of ophthalmology, including purchase and resale of ophthalmic devices and accessories for ophthalmological applications

Ophtec B.V. Schweitzerlaan 15 9728 NR Groningen The manufacture and distribution of medical devices for the area of ophthalmology, including purchase and resale of ophthalmic devices and accessories for ophthalmological applications

Addendum expiry date: 1 July 2024 Addendum effective date: 1 July 2021