

CERTIFICATE

Number: 2139589

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

Oté Holding B.V.

Vluchtoord 38
5406 XP Uden
Netherlands

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

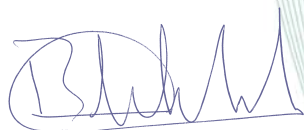
Scope:

Design, development, manufacture and distribution of contact lens and eye care products.
Distribution of soft contact lenses.

Certificate expiry date: 1 July 2027
Certificate effective date: 17 November 2025
Certified since: 1 July 2012

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.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed.



ADDENDUM

To certificate: 2139589

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

Oté Holding B.V.

Vluchtoord 38
5406 XP Uden
Netherlands

Certified organization(s) and/or locations:

Different scope

I-Care Vision B.V.
Faradaystraat 14
6718 XT Ede
Netherlands

Design, development, manufacture and distribution of contact lens and eye care products.
Distribution of soft contact lenses.

TEGE Pharma B.V.
Minervum 7384
4817 ZH Breda
Netherlands

Design, development, manufacture and distribution of contact lens and eye care products.
Distribution of soft contact lenses.

Melleson Pharma BV
Minervum 7384
4817 ZH Breda
Netherlands

Design, development, manufacture and distribution of contact lens and eye care products.
Distribution of soft contact lenses.

Oté Pharma Sol B.V.
Vluchtoord 38
5406 XP Uden
Netherlands

Design, development, manufacture and distribution of contact lens and eye care products.
Distribution of soft contact lenses.

Barnaux Healthcare B.V.
Vluchtoord 38
5406 XP Uden
Netherlands

Design, development, manufacture and distribution of contact lens and eye care products.
Distribution of soft contact lenses.

Addendum expiry date: 1 July 2027
Addendum effective date: 17 November 2025