EC CERTIFICATE

Number: 2113863CE06

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Oté Pharma Sol B.V.

Vluchtoord 38
5406 XP Uden
The Netherlands

For the product category(ies)

Lubricant eye drops for long term use

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2113863CN, initially dated 10 July 2018
Addendum, initially dated 3 December 2018

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 July 2023
Issued for the first time: 3 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2113863CE06

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Lubricant eye drops for long term use

Issued to:

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

This certificate covers the following product(s):

Variants:

- 042.xx Eye drop with Dexpanthenol
- 072.xx Eye drops 0.1% HA
- 073.xx Eye drops 0.2% HA
- 080.xx Eye drops Dexpanthenol

Initial date: 3 December 2018
Revision date: 28 April 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager