

# Declaration of Conformity to the requirements of MDD 93/42/EEC

For

## Contact Lens Care Products: Multipurpose Solutions and Cleaning Solutions

Record Title: DOC OTE Group 1 and 2 solutions  
Document ID: TF1.00.3143.002 Revision 02

### 1. Issuer's name and address

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Address : Vluchtoord 38  
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### 2. Additional information: Notified body

Name : Dekra Certification B.V.  
Address : Meander 1051, 6825 MJ Arnhem  
P.O. Box 5185, 6802 ED Arnhem  
The Netherlands  
Notified body no : 0344

### 3. Quality management System

This declaration is based on the application of the Quality System approved for the certification scopes listed in 2113863CE01 in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II is described in the said CE Marking of Conformity Certificates issued and delivered by DEKRA Certification B.V..  
The Quality Management System of Oté Pharma Sol B.V. is certified by DEKRA Certification B.V. for compliance with EN ISO 13485:2016 under 2187393:

#### 4. Object of the declaration

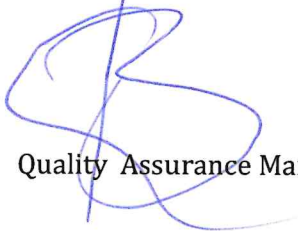
We, Oté Pharma Sol B.V., hereby declare that the distributed CE marked products, specified in the product list below (table 1) are conform to the products covered by the "CE Marking of Conformity Certificate" with reference numbers listed below and delivered by DEKRA Certification B.V., notified body identification number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

Table 1 Product overview

Multipurpose solutions and cleaners	Main product ID	Trade name
<b>All-in-One Solution</b>	001	Oté Twins
<b>Neutralising solution</b>	002	1-2-3 Safe
<b>Hydrogen peroxide solution</b>	003	1-2-3 Perox
<b>Hydrogen peroxide solution</b>	003	Oté One Step
<b>Preserved buffered isotonic sodium chloride solution</b>	004	Oté Saline C
<b>Buffered isotonic sodium chloride solution</b>	005	Oté Saline NT
<b>Isotonic Sodium Chloride 0,9% solution</b>	008	Oté Saline
<b>All-In-One-Solution VC</b>	009	Oté Fine
<b>Cleaner</b>	010	Oté Clean
<b>Multifunctional solution</b>	014	1-2-3 AIO No Rub
<b>Multifunctional solution</b>	014	Oté Twins Active
<b>Multifunctional Solution HS</b>	016	Oté Hydro-Shield
<b>All-In-One Soft B5</b>	025	Oté B5 Aqua
<b>Cleaner intensive</b>	029	Oté Pure
<b>Multi Sol-Comfort</b>	045	1-2-3 Sensation
<b>Multi Sol-Comfort</b>	045	Oté Sensation

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb meet the provisions of the EC-Directive which apply to them. For the compliance to the requirements of Annex II of the Medical Device Directive MDD 93/42/EEC, Oté Pharma Sol B.V. holds a valid CE certificate for the contact lens care solutions. All solutions are classified as class IIb devices, by application of rule 5 and rule 15 of Annex IX of the MDD 93/42/EEC.

Sharon de Bruin



Quality Assurance Manager

Date of release:

30 oct 2023