FINNSUSP

Appendix 5 to the original

DECLARATION OF CONFORMITY of Puro Suoja issued on 17th June 2020

We **Oy Finnsusp Ab**
Pääskykalliontie 5
21420 Lieto, Finland

declare under our sole responsibility that the medical device Puro Suoja which is also branded as:

The Eye Doctor Advanced Triple Action Eye Drops,
which is preservative-free dry eye drop,
filled in a multidose OSD, 10 ml,
whose device identifying type number is F0017,
classification is IIb sterile device and
classification rules that are applied are 5 and 15 under the Medical Device Directive 93/42/EEC

complies with the applicable requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EC and as described in the Technical file of the product. The Quality Management System for the design, manufacture and final inspection of the aforesaid product has been evaluated by the Notified Body Eurofins Electric & Electronics Finland Oy. Registration Number 0537.

Harmonised standards applied:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 13408-1:2015, EN ISO 13408-2:2018, EN 556-2:2015, EN ISO 10993-1:2009+AC:2010, EN ISO 10993-5:2009, EN ISO 10993-18:2020, EN ISO 10993-23:2021, EN ISO 11737-2:2020, EN ISO 15223-1:2016, EN 17141:2020
Conformity assessment route:	Annex II, Full Quality Assurance System
Notified body:	Eurofins Electric & Electronics Finland Oy, formerly named as: Eurofins Expert Services Oy, Finland
Original approval of EC Certification:	3rd October 2019
Current Certificate Nº.:	C-01-1190-724-20
Expiry of the current EC Certificate:	26th May 2024

Lieto, 17th January 2024

VAT FI 0305 7387 Oy Finnsusp Ab Lieto FINLAND

Heidi Hirviniemi
Quality Director
Oy Finnsusp Ab

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CERTIFIED MANAGEMENT SYSTEM eurofins ISO 13485 DQS MED Quality Management ISO 13485