DECLARATION OF CONFORMITY

A.Vogel Oogdruppels / Eye drops

We, A.Vogel B.V., hereby declare, in our sole responsibility, that the distributed CE-marked product, specified in the annexed product list, *i.e.* A.Vogel Oogdruppels (including the identical products with internationally translated product names), will be covered by the "CE-Marking of Conformity Certificate" delivered by the German notified body ECM (identification number CE0481), and conform to the required technical documentation, in accordance with Annex V/VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993 including all amendments, concerning medical devices.

In addition, we ensure and declare, in our sole responsibility, that the manufactured CE-marked product, as mentioned, and falling within Class IIa, meets the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in Annex V will be described in the said CE-Marking of Conformity Certificate, issued and delivered by ECM (notified to EC under 0481).

Certificate: A quality assurance system, according to DIN EN ISO 13485:2016 "Medical devices — Quality management systems — Requirements for regulatory purposes, for the: Design and development, production, distribution and sales of fluid and semi solid medical devices has been established and implemented.
Report Number: 455-18-1114 ; Registered under: Z/20/04643E ; Valid until March 31st, 2022

Certificate: Production Quality Assurance System Approval Annex V of the Directive on Medical Devices
Report Number: 455-18-1114 ; Registered under: Z/20/04644E ; Valid until: January 18th, 2021

This Declaration of Conformity covers *A.Vogel Oogdruppels (including the identical products with internationally translated product names)* as specified in the product list belonging to this declaration, and is valid for all products concerned, bearing the CE-marking and manufactured at the following site(s):

Manufacturer
A.Vogel B.V.
J.P. Broekhovenstraat 16
8081 HC ELBURG
The Netherlands

Prepared by:	Signature and date	Approved and signed by:	Signature and date
Responsible Document Owner **M.J.P. Lenczowski**	13-02-2020	Qualified Person **D-J. van Unen**	14-02-2020

Elburg, 2020/02/13

Signature authorised person
Dr. M.J.P. Lenczowski
Medical and Regulatory Affairs / Drug Safety Officer / EU QP Pharmacovigilance
A.Vogel B.V.
J.P. Broekhovenstraat 16
8081 HC ELBURG
The Netherlands

Annex: TF 3.14.3-2-Eye drops-DoC Product List