



# EC Declaration of Conformity

**Manufacturer:** innomedis AG, Walther-Rathenau-Str. 5, 50996 Köln, Germany  
**Name of Product:** ocuvers drops Gel 10ml  
**Article-code:** 800026  
**LOT:** Y0234  
**Production date:** 20.07.2020  
**Expiry date:** 2022-06  
**Type of product:** Eye drops  
**Classification:** Class IIb, Rule 15, in according with the Annex IX of the MDD 93/42/EEC and following modifications

We herewith declare under our sole responsibility that:

1. The above mentioned device meets the provisions of the Medical Device Directive 93/42/EEC (Annex II), and following modifications (EC Certificate No Z/16/03877E issued by the Notified Body ecm GmbH, Bismarckstr. 106, 52066 Aachen, Germany, ID 0481) through the application of its relevant European Standards.
2. All supporting documentation is retained by the manufacture in the Technical File STED.04 and is stored for 5 years after the last date of the product manufacture.
3. All the development and manufacture steps of the above mentioned device fulfill the requirements of the Company Quality Management System according to the requirements of the Annex II of the MDD 93/42/EEC and following modifications.
4. The Quality Management System fulfills the requirements of the European standard ISO 13485. This is certified by the Notified Body ecm – ID 0481 (certificate n° Z/15/04288E).
5. Innomedis has notified to the Competent Authorities that the device is currently commercialized, on the purpose to guarantee the proper post-market surveillance.
6. The present declaration is subject to the validity of the EC certificate no. Z/16/03877E MDD issued by the Notified Body ecm and lasts until the expiration date, unless significant changes made to the device or to the device manufacturing process.
7. The medical device is marketed in sterile conditions.

Köln, 15<sup>th</sup> September 2020

innomedis AG  
Lars Hünermann  
Managing Partner / Regulatory Affairs

# Certificate of Analysis

**Manufacturer:** innomedis AG, Walther-Rathenau-Str. 5, 50996 Köln, Germany  
**Name of Product:** ocuvers drops Gel 10ml  
**Article-code:** 800026  
**LOT:** Y234  
**Production date:** 20.07.2020  
**Expiry date:** 2022-06  
**Active Ingredient:** Sodium hyaluronate 0,3%  
**Type of product:** Eye drops  
**Classification:** Class IIb, Rule 15, in according with the Annex IX of the MDD 93/42/EEC and following modifications

The raw materials used to conform to the Ph. Eur. and/or the specifications declared on the Technical Product File **STED 04**.

Tests	Test Method	Specifications	Results	Released
pH	IdL. 08.25	7.20 ± 0.20	7.23	Yes
Osmolarity	IdL. 08.26	300 ± 30 mOsm/Kg	307 mOsm/Kg	Yes
Viscosity	IdL. 08.28	≥ 12 cPs – 25 °C	17.6 cPs	Yes
Extractable volume	IdL. 08.40	≥ 9.8 ml	10.2 – 10.3 ml	Yes
Packaging	IdL. 08.40	Complies with standard	Comply	Yes
Sterility (in compliance with pharmacopea)	IdL. 08.18	Sterile	Sterile	Yes

Köln, 15<sup>th</sup> September 2020

innomedis AG  
 Lars Hünermann  
 Managing Partner / Regulatory Affairs