

## EC DECLARATION OF CONFORMITY

according Annex II MDD 93/42/EEC

**Manufacturer:** OMISAN farmaceutici s.r.l. Via G. Galilei snc, 00012 Guidonia Montecelio, Roma

Medical Device Trade Name	Omisan Technical File Reference	Class (rule)	Product code	Lot Number	Quantity
OCUVERS DROPS LIPIX 10 ml	<b>TF-LSL - Technical File Liposomal Solutions Line</b>	II b (rule 15)	PF1018	BB32205	5.184 pcs

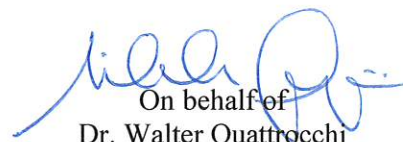
We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

### General applicable Directives and harmonized standards:

Council Directive 93/42/EEC of 14 June 1993 and further amendments concerning medical devices, Council Directive 2007/47/EEC of 5 September 2007 and further amendments concerning medical devices, EN ISO 13485:2016, EN ISO 14971:2012, UNI EN CEI ISO 15223-1: 2017, EN 556-2:2015, UNI CEI EN 1041:2013, UNI EN ISO 10993-1:2010.

CE Mark was granted by the Notified Body: **IMQ S.p.A.** (Via Quintiliano, 43 – 20138 Milano - Italy) and the Certificate number is **1760/MDD**.

Rome, 19/04/2023

  
On behalf of  
Dr. Walter Quattrocchi  
Technical Manager