innomedis | AG
BETTER VISION

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CE Declaration of Conformity

Manufacturer:	innomedis AG, Walther-Rathenau-Str. 5, 50996 Köln, Germany
Name of Product(s):	ocuvers spray lipostamin
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 product 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 STP.20 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 product fulfill the prescriptions reported in the society Quality Management System according with 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 and it is certified by the Notified Body ecm – ID 0481 (certificate n° Z/18/04288E).
5. Innomedis has notified to the Competent Authorities to have put on the market the above mentioned product to guarantee the post-market surveillance.
6. The present declaration is subject to the validity of the EC certificate No. Z/16/03877E MDD, unless significant changes made to the product or to the product manufacturing process.

The present declaration is referred to the Medical Device ***ocuvers spray lipostamin (art. 800008 / LOT xxx)*** and lasts until the expiration date of the EC Certificate No Z/16/03877E issued by the Notified Body ecm.

Köln, 27th August 2018

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