

DECLARATION OF CONFORMITY

according Annex II MDD 93/42/EEC

Manufacturer: Omisan farmaceutici S.r.l.u. - Via G. Galilei snc, 00012 Guidonia Montecelio, Roma
Medical device: Contact lens care solutions
Reference: Technical File TF-LSU
Variant code: LSU02
Trade name: OFTYLL MONOGREEN 360 ml
OFTYLL MONOGREEN S.K. 100 ml
OFTYLL MONOGREEN 500 ml
OFTYLL MONOGREEN 50 ml

Omisan farmaceutici S.r.l.u. declares that the above mentioned medical devices are in compliance with the following directives:

Council **Directive 93/42/EEC** of 14 June 1993 and further amendments concerning medical devices, and Council **Directive 2007/47/EEC** of 5 September 2007 and further amendments concerning medical devices

Conformity assessment procedure:

according to annex II, excluding requirements of section 4 of the Directive named above

Classification

according to annex IX of the Directive named above:
Class IIb, rule 15

Relevant harmonized standards

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.

The related Technical documentation is kept from the manufacturer and available to the Competent Authorities and to the Notified Body.

Omisan farmaceutici S.r.l.u. has developed a systematic procedure for the vigilance and post-market surveillance of medical devices in object according to the requirements of Regulation (EU) 2017/745 and MED.DEV. 2.12/1, Law Decree 37/2010 and the Law Decree 46/97.

Notified Body: IMQ S.p.A. (Via Quintiliano 45 – 20138 Milano - Italia)
EC certificate N°: 1760/MDD
EC Certificate Emission date: 2015-03-11
EC Certificate Updated: 2021-05-24
EC Certificate Expiry date: 2024-05-26

Guidonia Montecelio (RM), 10/04/2024



Dr. Walter Quattrocchi
Person Responsible for Regulatory Compliance