

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: Wetting and lubricating ophthalmic solutions
Reference: Technical File TF-LSO
Variant code: LSO05
Trade name: CALENDOFTYLL 15 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, 10/04/2024



Dr. Walter Quattrocchi
Person Responsible for Regulatory Compliance