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:	**Wetting and lubricating ophthalmic solutions**
Reference:	**Technical File TF-LSO**
Variant code:	**LSO09**
Trade name:	**OFTYLLA 15 ml**

Omisan farmaceutici srl 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 srl undertakes to institute and keep up to date, a systematic procedure according to the requirements of MED.DEV. 2.12/1, Italian DM 2009 and the Law Decree 46/97 to review experience gained on our medical devices in the post production phase, to implement appropriate means to apply any necessary corrective action and to notify the Competent Authorities and the Notified Body of each reportable events.

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:	**2020-07-03**
EC Certificate Expiry date:	**2024-05-26**

Rome, 04/02/2021

Dr. Walter Quattrocchi
Technical Manager

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