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:	**LSO33**
Trade name:	**SODYAL INTENSIVE 10 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

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