

**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:** LSO25S  
**Trade name:** NEBUVIS REHYDRATING EYES SPRAY 10 ml

Omisan farmaceutici S.r.l.u. declares that the above mentioned medical device is 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,

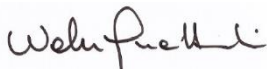
UNI CEI EN 1041:2013, UNI EN ISO 10993-1:2010.

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.

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

Guidonia Montecelio (RM), 10/04/2024



Dr. Walter Quattrocchi  
Person Responsible for Regulatory Compliance