Omisan
farmaceutici

DECLARATION OF CONFORMITY

according Annex VII MDD 93/42/EEC

Manufacturer:	**OMISAN farmaceutici s.r.l.** - *Via G. Galilei snc, 00012 Guidonia Montecelio, Roma*
Medical device:	**Ophthalmic Wipes**
Trade name:	**GARZE BUSTINE SINGOLE SFUSE Aloe + HA**

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

Classification
according to annex IX of the Directive named above:
Classe I
Relevant harmonized standards
EN ISO 14971:2012, UNI EN CEI ISO 15223-1: 2017,
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.

Omisan farmaceutici srl undertakes to institute and keep up to date, a systematic procedure according to the requirements of MEDDEV. 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 of each reportable events.

Rome, 27/11/2020

Dr. Walter Quattrocchi
Technical Manager

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