

DECLARATION OF CONFORMITY

according Annex VII MDD 93/42/EEC

Manufacturer: Omisan farmaceutici S.r.l.u. - Via G. Galilei snc, 00012 Guidonia Montecelio, Roma

Medical device: Ophthalmic Wipes

Trade name: Ocucers Wipes 20pcs

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

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 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.

Rome, 25/05/2021



Dr. Walter Quattrocchi
Person Responsible for Regulatory Compliance