

Brescia, 5th October 2021

TO WHOM IT MAY CONCERN

REF.: WASP® AND WASPLAB® AUTOMATION - CONTAINERS, CONSUMABLES AND SPARE PARTS

Copan Wasp S.r.l. ("Copan"), manufacturer of the Wasp® and WaspLab® instruments (the "Systems"), declares that -in order to grant the reliability of the diagnostic results to which the Systems contribute and allow their safe and correct functioning- any consumables and spare parts must be supplied, and technical support must be provided, exclusively by Copan (or its authorized distributors); or, if supplied by third parties, they must be approved in writing by Copan.

In case non-approved items are processed or used in combination with the Systems, the manufacturer's warranty is void and Copan does not accept any liability for damages occurred to the Systems or caused to the users or third parties; under the same terms, Copan will not bear any responsibility regarding the accuracy of the diagnostic results obtained via the use of Wasp® or WaspLab® in combination with products that are not made or approved by Copan.

These terms and conditions apply also to the provision of technical services from entities other than Copan or its authorized Distributors and service providers.

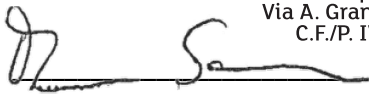
Copan retains the right to refuse testing and/or approving the use of products (with Wasp® and WaspLab® instruments) that may infringe Copan's patents. Additionally, anywhere such intellectual property is granted protection, Copan reserves the right to take legal action against any party who manufactures, imports, uses, sells, or offers for sale products covered by Copan's patented technology without permission/license from Copan.

Copan concerns are primarily safety of the operators, reliability of the diagnostics results obtained with the concurrence of the system and performance/stability/durability of the instrument itself.

Systems and their components, as well as culture plates, are classified as IVD; the primary containers are Medical Devices (e.g., swabs) or IVD (e.g., urine containers); each of them and their combined use are subject to the applicable Directives and Regulations, which impose significant responsibility to the manufacturer also from a regulatory perspective.

Respectfully, any declaration issued by third parties, including end-users, manufacturers or vendors, has no relevance to Copan as a manufacturer. Copan is the only entity entitled and competent to declare which items are approved or not for use on Wasp® or WaspLab®, which are fully developed, manufactured and sold by Copan. Due to the potential regulatory and legal liabilities at stake, we believe Copan position is well founded.

Copan Wasp S.r.l.



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