

EC-DECLARATION OF CONFORMITY
WASP®
IN VITRO DIAGNOSTIC DEVICE

Manufacturer: COPAN WASP S.r.l.
Via Achille Grandi, 32
25125 Brescia

European Representative: N.A.

Product Identification: WASP®
(See the attached product-list for instrument, modules & accessories)

Classification
(according to 98/79/EC): General/Other IVD

Conformity assessment
route: Annex III (IVDD)

Under our own sole responsibility, we herewith declare that the products as specified in the product-list meet the provisions of the Council Directive 98/79/EC for in vitro medical devices and following amendments. All supporting documentation is retained under the premises of the manufacturer.

This declaration is supported by the Quality System certification based on the standard **EN ISO 13485:2016**
Quality Management System certificate

Valid until: 01/04/2023

PRODUCT-LIST**WASP®**

PRODUCT CODE	PRODUCT NAME
W086	WASP®
W086-40N	Slide Prep Evo™
W086-090	PIPETTOR MODULE™
WO086-80-2001	Advanced AST System
W086-020	Radian™ In-Line Carousel
WR086-03-0001	Disposable Drip Tray with absorbing sponge
WR086-50-0001	Disposable New Pad for Docking Station
WR086-03-0004	Disposable Rejection Bin Pad
WR086-03-0005	Loop Cleansing Solution 5ml
WR086-03-0019	Loop Cleansing Solution 10ml
WR086-61-0014	Disposable Drip Tray for Broth
WR086-03-0014	WASP® Microscope Slide
WR086-03-0600	Double Nichrome Loop 1 µL rounding
WR086-03-0601	Double Nichrome Loop 10µL
WR086-03-0602	Double Nichrome Loop 30µL
WR086-03-0603	Twin Double Nichrome Loop 1µL rounding
WR086-03-0604T	Nichrome 30µL Loop/Spreader
WR086-03-1015	PBS Solution 2ml
WR086-03-1023	WASP® QC TSB Tube
WR092-01-0607T	Double Spreader

Place, Date of Issue:

Brescia, 01/04/2021



Mario Savarese
Site Managing Director