



**EU - DECLARATION OF CONFORMITY**  
**IVDR 2017/746**  
**TSB™**

<b>MANUFACTURER:</b>	<i>Copan Italia S.p.A., Via F. Perotti 10, 25125 Brescia, Italy</i>
<b>SRN NUMBER:</b>	<i>IT-MF-000022535</i>
<b>NAME OF THE DEVICE:</b>	<i>TSB™ (See the attached list of product code)</i>
<b>INTENDED PURPOSE:</b>	<i>COPAN TSB broth is a ready-to-use nutrient medium that supports the growth of a wide variety of aerobic and facultative aerobic/anaerobic bacteria originating from clinical specimens or specimens isolated on a generic or selective medium.</i>
<b>BASIC UDI-DI:</b>	<i>80533260BD0410AM0047W</i>
<b>CLASSIFICATION ACCORDING TO IVDR 2017/746 (ANNEX VIII):</b>	<i>Class A non-sterile, Rule 5</i>
<b>CONFORMITY ASSESSMENT ROUTE:</b>	<i>Annex II + Annex III (Annex IV)</i>
<b>NOTIFIED BODY:</b>	<i>N.A.</i>
<b>EU CERTIFICATE NUMBER AND VALIDITY:</b>	<i>N.A.</i>

Under our own sole responsibility, we hereby declare that the products, as specified in the product list, meet the provisions of Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices. 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.**



**PRODUCT-LIST**  
**TSB™ kit**

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
468CE02*	Tsb kit 2ml + 2 Regular Flocked

*\*This kit contains the Medical Device FLOQSwabs® and/or CLASSIQSwabs™ manufactured by COPAN ITALIA S.p.A, located in via F. Perotti 10, 25125 Brescia, Italy. This product satisfies the Essential Requirements of the Directive 93/42/EEC dated 14th June 1993, concerning Medical Devices, Annex I and following updates, and it is covered by the "EC-certificate-Full Quality Assurance System-Annex II of MDD 93/42/EEC" No. G1 073936 0014 REV.03 issued on by the Notified Body (Identification N.0123) TÜV SÜD PRODUCT SERVICE GmbH, Ridlerstraße 65, 80339 München – Germany.*

Place, Date of First Issue: Brescia, 18/05/2022

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Elisabetta Zanella  
Chief Regulatory Officer  
COPAN ITALIA S.p.A