Copan
innovating together

EU - DECLARATION OF CONFORMITY
IVDR 2017/746
GN Broth™

MANUFACTURER:	*Copan Italia S.p.A., Via F. Perotti 10, 25125 Brescia, Italy*
SRN NUMBER:	*IT-MF-000022535*
NAME OF THE DEVICE:	*GN Broth™* *(See the attached list of product code)*
INTENDED PURPOSE:	*Copan GN broth is an enrichment and selective medium for enteric GramNegative organisms, especially salmonelle and shigelle.*
BASIC UDI-DI:	*8053326ED0320AM0048T*
CLASSIFICATION ACCORDING TO IVDR 2017/746 (ANNEX VIII):	*Class A non-sterile, Rule 5*
CONFORMITY ASSESSMENT ROUTE:	*Annex II + Annex III (Annex IV)*
NOTIFIED BODY:	*N.A.*
EU CERTIFICATE NUMBER AND VALIDITY:	*N.A.*

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.**

Copan
innovating together

PRODUCT-LIST
GN Broth™ in bulk

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
085CU.A	GN gram negative enrichment broth 4ml

Place, Date of First Issue: Brescia, 18/05/2022
Place, Current Version Issued on: Brescia, 31/01/2023

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