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EU - DECLARATION OF CONFORMITY
IVDR 2017/746
UriSponge™

44p.d.

MANUFACTURER:	*Copan Italia S.p.A., Via F. Perotti 10, 25125 Brescia, Italy*
SRN NUMBER:	*IT-MF-000022535*
NAME OF THE DEVICE:	*UriSponge™* *(See the attached list of product code)*
INTENDED PURPOSE:	*Urine transport and preservation system.* *Copan Urisponge™ - Urine Collection, Transport and Preservation System is intended for the transport and preservation of urine specimens, transferred from their initial container, from the colle site to the testing laboratory. In the laboratory, Urisponge™ spec are processed using standard clinical laboratory operating proce for the cultivation of uropathogenic bacteria and yeasts.*
BASIC UDI-DI:	80533260CD0160AM0019K
CLASSIFICATION ACCORDING TO IVDR 2017/746 (ANNEX VIII):	*Class A sterile, Rule 5*
CONFORMITY ASSESSMENT ROUTE:	*Annex IX, Chapters I and III (Quality Management System)*
NOTIFIED BODY:	*TÜV SÜD PRODUCT SERVICE GmbH,* *Ridlerstraße 65, 80339 München-Germany,* *Notified Body Identification Number 0123*
EU CERTIFICATE NUMBER AND VALIDITY:	*V11 073936 0015 Rev.00* *Valid until 18/04/2027*

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

PRODUCT CODE	PRODUCT DESCRIPTION / INTENDED PURPOSE
802CE.A	UriSponge™ Urine transport and preservation system, vial 12x80

Place, Date of First Issue: Brescia, *27/02/2023*
Place, Current Version Issued on: Br*escia, 02/08/2023*

Elisabetta Zanella
Chief Regulatory Officer
Copan Italia S.p.A.