

**EC-DECLARATION OF CONFORMITY**  
**Dry Fiber Swabs “Copan Italia S.p.A.”**  
**MEDICAL DEVICE**

**Manufacturer:** *Copan Italia S.p.A.  
Via Perotti, 10  
25125 Brescia, Italia*

**European Representative:** *N.A.*

**Product family:** *Dry Fiber swabs Copan Italia S.p.A.  
(See the attached product list “Dry Fiber swabs”)*

**Classification  
(according to 93/42/EEC):** *Class IIa, Rule 6*

**Conformity assessment  
route:** *Annex II, excluding Section 4 (MDD)*

*Under our own sole responsibility, we herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for 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.**

**Notified Body:** *TÜV SUD PRODUCT SERVICE GmbH,  
Ridlerstraße 65, 80339 München-Germany,  
Notified Body Identification Number 0123*

**EC Certificate(s):** *G1 073936 0014 Rev. 03*

**Valid until:** *26<sup>th</sup> May 2024*

**PRODUCT LIST*****Dry Fiber Swabs “Copan Italia S.p.A.”***

<b>Product Code</b>	<b>Description</b>
<b>164KS01.CA</b>	STERILE PLASTIC APPLICATOR POLYESTER TIPPED INDIVIDUALLY WRAPPED
<b>165KS01.CA</b>	STERILE WOODEN APPLICATOR COTTON TIPPED INDIVIDUALLY WRAPPED
<b>167KS01.CA</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
<b>170KS01.CA</b>	ALUMINIUM APPLICATOR RAYON TIPPED STERILE IND. WRAPPED
<b>175KS01.CA</b>	STERILE ALUMINIUM APPLICATOR POLYESTER TIPPED INDIVIDUALLY WRAPPED
<b>150C</b>	PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
<b>154C</b>	PLAIN SWAB STERILE WOODEN APPLICATOR RAYON TIPPED
<b>155C</b>	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
<b>155CS01</b>	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED IND. WRAPPED
<b>159C</b>	PLAIN SWAB STERILE PLASTIC APPLICATOR POLYESTER TIPPED
<b>160C</b>	PLAIN SWAB STERILE ALUMINIUM APPLICATOR RAYON TIPPED
<b>162C</b>	PLAIN SWAB STERILE ALUMINIUM APPLICATOR POLYESTER TIPPED
<b>163C</b>	PLAIN SWAB STERILE WOODEN APPLICATOR CARDED COTTON
<b>164C</b>	PLAIN SWAB STERILE PAPER APPLICATOR COTTON TIPPED
<b>167CS01</b>	PLAIN DUAL SWAB PLASTIC APPLICATOR RAYON TIPPED IND. WRAPPED
<b>168C</b>	PLAIN SWAB STERILE TWISTED APPLICATOR RAYON TIPPED
<b>172C</b>	PLAIN SWAB STERILE SOFT ALUMINIUM APPLICATOR
<b>184C</b>	PLAIN SWAB MINITIP STERILE RAYON TIPPED
<b>185C</b>	PLAIN SWAB PLASTIC MINITIP STERILE POLYESTER FIBER
<b>451C</b>	PLAIN SWAB STERILE, WOODEN APPLICATOR RAYON TIPPED IN TUBE
<b>456C</b>	PLAIN SWAB STERILE, PLASTIC APPLICATOR RAYON TIPPED IN TUBE
<b>8150C</b>	PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
<b>8155C</b>	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
<b>1U028S01</b>	STERILE PLASTIC APPLICATOR RAYON TIP BP 100MM INDIVIDUALLY WRAPPED
<b>1U026S01</b>	CLEANING SWAB PLASTIC APPLICATOR RAYON TIP IND. WRAPPED
<b>167KS01TB</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED BLUE CAP IND. WRAPPED
<b>8150CIS</b>	PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
<b>8154CIS</b>	PLAIN SWAB STERILE WOODEN APPLICATOR RAYON TIPPED
<b>8155CIS</b>	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
<b>8155CLH</b>	PLAIN SWAB PLASTIC APPLICATOR STERILE RAYON TIPPED
<b>8160CIS</b>	PLAIN SWAB STERILE ALUMINIUM APPLICATOR RAYON TIPPED
<b>8164CIS</b>	PLAIN SWAB STERILE PAPER APPLICATOR COTTON TIPPED
<b>138CS01</b>	PLASTIC SWAB BP 33MM STERILE INDIVIDUALLY WRAPPED
<b>163KS01</b>	STERILE WOODEN APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED

<b>163KS02</b>	STERILE WOODEN APPLICATOR RAYON TIPPED 2 PCS PACKED
<b>163KS03</b>	STERILE WOODEN APPLICATOR RAYON TIPPED 3 PCS PACKED
<b>164KS01</b>	STERILE PLASTIC APPLICATOR POLYESTER TIPPED INDIVIDUALLY WRAPPED
<b>165KS01</b>	STERILE WOODEN APPLICATOR COTTON TIPPED INDIVIDUALLY WRAPPED
<b>166KS01</b>	PLASTIC APPLICATOR STERILE LONG 12,5 cm SINGLE WRAPPED
<b>167KS01</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
<b>167KS02</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED 2 PCS PACKED
<b>170KS01</b>	ALUMINIUM APPLICATOR RAYON TIPPED STERILE IND. WRAPPED
<b>175KS01</b>	STERILE ALUMINIUM APPLICATOR DACRON TIPPED INDIVIDUALLY WRAPPED
<b>184CS01</b>	Ultra-Thin minitip swab, rayon tip, sterile individually wrapped
<b>185CS01</b>	Ultra-Thin minitip swab, polyester tip, sterile individually wrapped
<b>302CS03</b>	PLASTIC APPLICATOR SWAB POLYESTER TIPPED STERILE 3 PCS PACKED
<b>164KS01.US</b>	STERILE PLASTIC APPLICATOR POLIESTER TIPPED INDIVIDUALLY WRAPPED
<b>16460KS01</b>	PLASTIC APPL. POLYESTER TIPPED PF60MM STERILE INDIVIDUALLY WRAPPED
<b>165KS01.US</b>	STERILE WOODEN APPLICATOR COTTON TIPPED INDIVIDUALLY WRAPPED
<b>165KS02</b>	STERILE WOODEN APPLICATOR COTTON TIPPED 2 PCS PACKED
<b>165KS100</b>	STERILE WOODEN APPLICATOR COTTON TIPPED 100 PCS PACKED
<b>165KS25</b>	WOODEN APPLICATOR COTTON TIPPED 25 PCS PACKED
<b>167AKS01</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
<b>167KS01.US</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
<b>167KS100</b>	STERILE PLASTIC APPLICATOR RAYON TIPPED 100 PCS PACKED
<b>167KS25</b>	PLASTIC APPLICATOR STERILE 25 PCS PACKED
<b>170KS01.US</b>	ALUMINIUM APPLICATOR RAYON TIPPED STERILE IND. WRAPPED
<b>175KS01.US</b>	STERILE ALUMINIUM APPLICATOR DACRON TIPPED INDIVIDUALLY WRAPPED
<b>1U054S01</b>	Regular Polyester Swab, breaking point 100mm
<b>1U059S01</b>	Regular Polyester Swab, marked breaking point 73mm
<b>1U060S01</b>	Regular Polyester Swab, marked breaking point 79mm

To all base code here before listed any prefix or suffix indicate only a customization regarding the packaging lay-out.

**Place, Date of Issue:** Brescia, 05<sup>th</sup> March 2021

Elisabetta Zanella  
Chief Regulatory Officer