

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: 26th May 2024

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

Product Code	Description
164KS01.CA	STERILE PLASTIC APPLICATOR POLYESTER TIPPED INDIVIDUALLY WRAPPED
165KS01.CA	STERILE WOODEN APPLICATOR COTTON TIPPED INDIVIDUALLY WRAPPED
167KS01.CA	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
170KS01.CA	ALUMINIUM APPLICATOR RAYON TIPPED STERILE IND. WRAPPED
175KS01.CA	STERILE ALUMINIUM APPLICATOR POLYESTER TIPPED INDIVIDUALLY WRAPPED
150C	PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
152C	CHARCOAL PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
154C	PLAIN SWAB STERILE WOODEN APPLICATOR RAYON TIPPED
155C	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
155CS01	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED IND. WRAPPED
157C	CHARCOAL PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
159C	PLAIN SWAB STERILE PLASTIC APPLICATOR POLYESTER TIPPED
160C	PLAIN SWAB STERILE ALUMINIUM APPLICATOR RAYON TIPPED
162C	PLAIN SWAB STERILE ALUMINIUM APPLICATOR POLYESTER TIPPED
163C	PLAIN SWAB STERILE WOODEN APPLICATOR CARDED COTTON
164C	PLAIN SWAB STERILE PAPER APPLICATOR COTTON TIPPED
167CS01	PLAIN DUAL SWAB PLASTIC APPLICATOR RAYON TIPPED IND. WRAPPED
168C	PLAIN SWAB STERILE TWISTED APPLICATOR RAYON TIPPED
172C	PLAIN SWAB STERILE SOFT ALUMINIUM APPLICATOR
184C	PLAIN SWAB MINITIP STERILE RAYON TIPPED
185C	PLAIN SWAB PLASTIC MINITIP STERILE POLYESTER FIBER
451C	PLAIN SWAB STERILE, WOODEN APPLICATOR RAYON TIPPED IN TUBE
456C	PLAIN SWAB STERILE, PLASTIC APPLICATOR RAYON TIPPED IN TUBE
8150C	PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
8155C	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
1U028S01	STERILE PLASTIC APPLICATOR RAYON TIP BP 100MM INDIVIDUALLY WRAPPED
1U026S01	CLEANING SWAB PLASTIC APPLICATOR RAYON TIP IND. WRAPPED
167KS01TB	STERILE PLASTIC APPLICATOR RAYON TIPPED BLUE CAP IND. WRAPPED
8150CIS	PLAIN SWAB STERILE WOODEN APPLICATOR COTTON TIPPED
8154CIS	PLAIN SWAB STERILE WOODEN APPLICATOR RAYON TIPPED
8155CIS	PLAIN SWAB STERILE PLASTIC APPLICATOR RAYON TIPPED
8155CLH	PLAIN SWAB PLASTIC APPLICATOR STERILE RAYON TIPPED
8160CIS	PLAIN SWAB STERILE ALUMINIUM APPLICATOR RAYON TIPPED
8164CIS	PLAIN SWAB STERILE PAPER APPLICATOR COTTON TIPPED

138CS01	PLASTIC SWAB BP 33MM STERILE INDIVIDUALLY WRAPPED
163KS01	STERILE WOODEN APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
163KS02	STERILE WOODEN APPLICATOR RAYON TIPPED 2 PCS PACKED
163KS03	STERILE WOODEN APPLICATOR RAYON TIPPED 3 PCS PACKED
164KS01	STERILE PLASTIC APPLICATOR POLYESTER TIPPED INDIVIDUALLY WRAPPED
165KS01	STERILE WOODEN APPLICATOR COTTON TIPPED INDIVIDUALLY WRAPPED
166KS01	PLASTIC APPLICATOR STERILE LONG 12,5 cm SINGLE WRAPPED
167KS01	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
167KS02	STERILE PLASTIC APPLICATOR RAYON TIPPED 2 PCS PACKED
170KS01	ALUMINIUM APPLICATOR RAYON TIPPED STERILE IND. WRAPPED
175KS01	STERILE ALUMINIUM APPLICATOR DACRON TIPPED INDIVIDUALLY WRAPPED
184CS01	Ultra-Thin minitip swab, rayon tip, sterile individually wrapped
185CS01	Ultra-Thin minitip swab, polyester tip, sterile individually wrapped
302CS03	PLASTIC APPLICATOR SWAB POLYESTER TIPPED STERILE 3 PCS PACKED
164KS01.US	STERILE PLASTIC APPLICATOR POLIESTER TIPPED INDIVIDUALLY WRAPPED
16460KS01	PLASTIC APPL. POLYESTER TIPPED PF60MM STERILE INDIVIDUALLY WRAPPED
165KS01.US	STERILE WOODEN APPLICATOR COTTON TIPPED INDIVIDUALLY WRAPPED
165KS02	STERILE WOODEN APPLICATOR COTTON TIPPED 2 PCS PACKED
165KS100	STERILE WOODEN APPLICATOR COTTON TIPPED 100 PCS PACKED
165KS25	WOODEN APPLICATOR COTTON TIPPED 25 PCS PACKED
167AKS01	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
167KS01.US	STERILE PLASTIC APPLICATOR RAYON TIPPED INDIVIDUALLY WRAPPED
167KS100	STERILE PLASTIC APPLICATOR RAYON TIPPED 100 PCS PACKED
167KS25	PLASTIC APPLICATOR STERILE 25 PCS PACKED
170KS01.US	ALUMINIUM APPLICATOR RAYON TIPPED STERILE IND. WRAPPED
175KS01.US	STERILE ALUMINIUM APPLICATOR DACRON TIPPED INDIVIDUALLY WRAPPED
1U054S01	Regular Polyester Swab, breaking point 100mm

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, 26th March 2020



Elisabetta Zanella
Chief Regulatory Officer