

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Family Name	Code / Catalog Number
Sterile Absorbent Tipped Applicators	See Table 1

MANUFACTURER	
Name of Company	Address
Puritan Medical Products Company, LLC	31 School Street Guilford, ME 04443 USA

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Phone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 EmergoEurope@ul.com

CONFORMITY ASSESSMENT		
Device Classification		Directive
Class:	I Sterile	Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Annex V and Annex VII
Rule:	per MDD, Annex IX under Rule 5	

NOTIFIED BODY	
Name of Company	Certificate Reference(s)
British Standards Institution (BSI)	CE 02076

CE MARK	
Date CE mark was Affixed:	16 September 1998
Place, Date	Guilford, ME, USA 16 September 1998

Table 1

STERILE ABSORBENT TIPPED APPLICATORS CODE / CATALOG NUMBER LIST				
25-1000 1PD	25-3206-HB EMB 70MM	25-3320-H EMB 80MM	25-804 4PPC	25-806 1PRB 7870
25-1000 1PD BT 8090714	25-3206-U	25-3320-U	25-805 1PC TT FABUSA	25-806 1PRB 80/30
25-1001 1PD 504151	25-3206-U 20MM	25-3320-U EMB 100MM	25-805 1PD 09205098190	25-806 1PRB BD
25-1001 1PD MTL-01934	25-3206-U EC	25-3320-U EMB 80MM	25-805 1PR	25-806 1PRB GENZYME
25-1406 1PF 50	25-3306 2H	25-3406-H	25-806 10WC	25-806 1PRB GENZYME 91/11
25-1406 1PF BT	25-3306 2H BT	25-3406-H BT	25-806 10WCL	25-806 1PRLB
25-1406 1PF TT MC 50	25-3306 2U BT	25-3406-H ROCHE	25-806 1PA	25-806 1WA
25-1406 1PFB	25-3306-H	25-3406-HB	25-806 1PA BT	25-806 1WA BT
25-1406 1PFB 91/11 SW	25-3306-H 100/13	25-3406-U	25-806 1PAR	25-806 1WC
25-1504 PFB 8089500	25-3306-H BT	25-3406-U BT	25-806 1PC	25-806 1WC 7.5
25-1506 1PF 100	25-3306-U	25-3406-U RIB PRT SC 20MM	25-806 1PC BT	25-806 1WC BT
25-1506 1PF BT	25-3306-U BT	25-3506-H	25-806 1PC BT FABUSA	25-806 1WC EC
25-1506 1PF BT BL	25-3306-U FDNA	25-3506-U	25-806 1PC BT FABUSA-1	25-806 1WC FDNA
25-1506 1PF SLD 39/26	25-3306-U TT FDNA	25-3606 2H BT	25-806 1PC BT FABUSA-1GR	25-806 1WC GILL
25-1506 1PF SOLID	25-3316-H	25-3606 2U BT	25-806 1PC EC	25-806 1WCB 39/28
25-1506 1PF TT MC	25-3316-H 1217501	25-3606-H	25-806 1PD	25-806 1WD
25-1506 1PF TT MC 20	25-3316-H 60MM PRT	25-3606-H BT	25-806 1PD .213	25-806 1WR
25-1506 1PFB 100/10	25-3316-H BT	25-3606-U	25-806 1PD 09205098190	25-806 2PC
25-1506 1PFB 20	25-3316-H EMB 100 BT	25-3606-U BT	25-806 1PD 500561	25-806 2PC BLUE
25-1506 1PFB PK002196	25-3316-H EMB 79.5MM	25-3606-U BT FABUSA	25-806 1PD 7.5	25-806 2PC PINK
25-1506 1PFB SLD 1033500	25-3316-H EMB 80 BT	25-3606-U BT FABUSA-1	25-806 1PD BEC 100	25-806 2PC YELLOW
25-1506 1PFB SLD 20	25-3316-H EMB 99.5MM	25-3706-H	25-806 1PD BT	25-806 2PCB PINK 40/25
25-1506 1PFB SMO SC 79MM	25-3316-H LH-7-24	25-3706-H BT	25-806 1PD HOLOGIC	25-806 2PD
25-1506 1PFB TT 20171	25-3316-H NYL EMB 79.5MM	25-3706-H BT PK	25-806 1PD MTL-01933	25-806 2PD BT
25-1506 2PF BT	25-3316-H NYL EMB 99.5MM	25-3706-U	25-806 1PD SC 2 1/2	25-806 2PD ROCHE 30MM
25-1516 1PF SOLID CELLMARK	25-3316-U	25-3706-U BT	25-806 1PD SC ROCHE	25-806 2PD SC 3.875
25-1597 10PF	25-3316-U BT	25-3806-H	25-806 1PD SLD BT	25-806 2PR



Puritan
Quality since 1919

Puritan Medical Products Company, LLC
Declaration of Conformity Reference Number: 1002
Revision Number: 023
Sterile Absorbent Tipped Applicators

STERILE ABSORBENT TIPPED APPLICATORS CODE / CATALOG NUMBER LIST				
25-1605 1PSF RECT	25-3316-U EMB 100 BT	25-3806-H BT	25-806 1PD SLD MTL-02105	25-806 2PR BT
25-1607 1PF SC	25-3316-U EMB 79.5MM	25-3806-H BT PK	25-806 1PD SOLID	25-806 2PR TT
25-1616 1PF	25-3316-U EMB 80 BT	25-3806-U	25-806 1PD/3316-H EMB ROCHE	25-806 2PR TT 7784
25-1803 1PF	25-3317-H	25-3806-U BT	25-806 1PDB	25-806 2PRB TT 20228
25-1803 PFLB	25-3317-H 37/27/1	25-441357	25-806 1PDB 1500	25-806 2WA
25-1805 1PF RND	25-3317-H 77/13	25-441358	25-806 1PDB FP 7.5	25-806 2WC
25-1805 1PF RND AMNI	25-3317-H BT	25-443376	25-806 1PDB PK002078J	25-806 2WC S-21102
25-1805 1PF RND FDNA	25-3317-HB	25-443925	25-806 1PDB SLD 04862	25-806 2WC TT FDNA
25-1806 1PCF HS 8MM	25-3317-U	25-800 1PD 50	25-806 1PDB SLD ABON	25-806 2WD
25-1806 1PCSF HS 6MM	25-3317-U 190	25-800 1PD ALUM 50	25-806 1PDB SLD MTL-01931	25-806 3PDB
25-1906 10PF	25-3317-U 20	25-800 2PDB	25-806 1PDB SOLID	25-806 5WC
25-220690	25-3317-U ASAN	25-800 2PDBG	25-806 1PDB UNBRK	25-807 1PC EC
25-221607	25-3317-U BT	25-800 A 50	25-806 1PDS BINAX	25-807 W100
25-3000-H E30	25-3318-H	25-800 C 50	25-806 1PDS BT 500010895	25-808 1PR
25-3000-U E30	25-3318-H BT	25-800 D 50	25-806 1PDS PK002239	25-808 2PR
25-3206-H	25-3318-H BULK	25-800 R 50	25-806 1PDS SC	25-825 1WCS TT 3010806
25-3206-H 20MM	25-3318-U	25-801 A 50	25-806 1PR	25-825 1WCS TT FABUSA
25-3206-H 20MM BT	25-3318-U BT	25-801 D 50	25-806 1PR BT	25-825 1WCS TT K536
25-3206-H EC	25-3319-H	25-801 R 50	25-806 1PRB	25-826 2WD
25-3206-H EMB 33MM PHX	25-3319-H BT	25-801 R 5-7/8	25-806 1PRB 1277600	25-826 5WC
25-3206-H EMB 50MM	25-3319-HB	25-803 2PC	25-806 1PRB 250/10	
25-3206-H EMB 50MM PRT	25-3320-H	25-803 2PD BLUE	25-806 1PRB 250/10 UNB	
25-3206-H LH-11-10	25-3320-H EMB 100MM	25-803 2WC	25-806 1PRB 7814	



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Puritan Medical Products Company, LLC herewith declares under Annex V and Annex VII conformity assessment route; the above-mentioned product meets the provisions of the appropriate EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer and the notified body.

COMPANY REPRESENTATIVE: David Saari

POSITION: Person Responsible for Regulatory Compliance (PRRC)

SIGNATURE: David Saari **DATE:** 25/05/2021