



DEVICE DETAILS

NAME OF DEVICE	ABSORBABLE SURGICAL SUTURES
ESTABLISHMENT NAME	BACTIGUARD (SOUTH EAST ASIA) SDN. BHD.
ROLE OF ESTABLISHMENT	MANUFACTURER
REGISTRATION NO	GD3590252916
BRAND NAME	ECOSORB FAST
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	ECOSORB FAST IS AN ABSORBABLE, STERILE SUTURE MATERIAL, MADE OF POLY (GLYCOLIDE-CO-LACTIDE) (GLACOMER 91). ECOSORB FAST IS DYED VIOLET WITH THE FDA APPROVED DYESTUFF D & C VIOLET NO.2 TO MAKE IT UNIQUE, AND IT IS ALSO AVAILABLE UN-DYED IN ITS BEIGE COLOUR. THE BRAIDED SUTURE THREADS ARE COATED WITH GLACOMER 37 AND CALCIUM STEARATE SO THAT THEY GLIDE EASILY BUT REMAIN FIRM WHEN KNOTTING WITHOUT CAUSING A SAWING EFFECT. ECOSORB FAST FULFILLS ALL THE REQUIREMENTS OF THE PHARM. EUR AND FDA, FOR STERILE, SYNTHETIC, ABSORBABLE, BRAIDED SUTURES (EXCEPT DIAMETER, WITH A MAX. OVERSIZE IS 0.005MM FROM THE STANDARD)
DEVICE INTENDED PURPOSE	ECOSORB FAST IS INDICATED FOR USE IN SUPERFICIAL SOFT TISSUE APPROXIMATION OF THE SKIN AND MUCOSA, WHERE SHORT TERM WOUND SUPPORT IS REQUIRED. ECOSORB FAST IS SUITED FOR SKIN CLOSURE, EPISIOTOMY REPAIR AND CLOSURE OF LACERATIONS.
VALIDITY DATE OF REGISTRATION	30/08/2021 - 29/08/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F67RH17W
2	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F67RH13W
3	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F57RH17W
4	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F47RH17W
5	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F47RH20W
6	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37RH20W
7	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37RH260
8	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37RH26W

NO	NAME OF DEVICE	IDENTIFIER
9	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37RH30W
10	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F27RH26W
11	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F07RH26W
12	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F17RH30W
13	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F27RH30W
14	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F27RH35W
15	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F27RH40W
16	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29RH37W
17	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F39RH36W
18	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29RH36W
19	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F07RH36W
20	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	FA7RH40W
21	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F19RH40W
22	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F17RH40W
23	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F07RH40W
24	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F09RH40W
25	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F64CD11W
26	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F67CD12W
27	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F57CD12W
28	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F54CD12W
29	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F44CD12W
30	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F54CD13W
31	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F54CD16W
32	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F44CD16W
33	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F67CD17W
34	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F44CD19W

NO	NAME OF DEVICE	IDENTIFIER
35	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F34CD19W
36	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F57CD16W
37	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F47CD16W
38	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37CD16W
39	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F47CD19W
40	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37CD19W
41	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F47CD24W
42	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37CD24W
43	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F27CD24W
44	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F27CD30W
45	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29CD35W
46	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F64MD13W
47	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F54MD13W
48	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F54MD16W
49	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F09VH35W
50	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29VH35W
51	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F39VH35W
52	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29VH36W
53	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29VH39W
54	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F29VH45W
55	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F09VH370
56	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F09VH400
57	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F28-P010
58	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F2BVH35W
59	ECOSORB FAST (Absorbable, Synthetic, Braided, Poly (Glycolide-co-Lactide))	F37PD24W