

## NO IFU NEEDED BY WAY OF EXCEPTION

**Manufacturer: Henry Schein, Inc. - 135 Duryea Road Melville - New York 11747, USA**

Below non-sterile items come without Instruction for Use regarding handling, storage, transportation or disposal.

The COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Annex I, 13.1, reads: “...By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.”

The products are on the market for a long time without incidents. They are only used by trained dental professionals in dental practices or clinics. Therefore we consider that these items can be used safely without an IFU.

**Intended purpose of the medical device:**

Henry Schein, Inc. prophylaxis cups and brushes are for use by the Dentist or Hygienist for prophylaxis polishing of teeth, they are for single use only. These instruments are Class 2a Medical devices and are for use in the mouth only by (or under the instruction of) a qualified dental professional.

REF	Description
9008911	Nylon Brush, screw type
9008912	Natural Bristle Brush, screw type
9002632	Prophy brush, white nylon bristles, RA
9006524	Prophy brushes, blue (stiff / firm), latexfree
9006525	Prophy brushes, purple (medium), latexfree
9006526	Prophy brushes, pink (soft), latexfree
9008657	Prophy brushes, blue, pink and violet, 75 pcs total, latexfree
9008904	Prophy brushes, blue (stiff / firm), screw type, latexfree
9008905	Prophy brushes, purple (medium), screw type, latexfree
9008906	Prophy brushes, pink (soft), screw type, latexfree
9006521	prophy Cups, blue (stiff / firm), latexfree
9006522	prophy Cups, purple (medium), latexfree
9006523	prophy Cups, pink (soft), latexfree
9008907	prophy Cups, blue (stiff / firm), screw type, latexfree
9008908	prophy Cups, purple (medium), screw type, latexfree
9008909	prophy Cups, pink (soft), screw type, latexfree
9008658	Prophy cups, blue, pink and violet, 75 pcs total, latexfree
9008913	Prophy cups, snap on, white, latexfree
9008914	Prophy cups, screw type, white, latexfree
9008915	Prophy cups, RA, white, latexfree
9008917	mandrel for snap on prophy cups, latexfree
9881917	Prophy Cups, snap-on type blue (stiff / firm), latex free
9881918	Prophy Cups, snap-on type purple (medium), latex free
9881919	Prophy Cups, snap-on type pink (soft), latex free
9882647	Pencil Brush nylon (pointed)
5722518	Prophy Cups, RA, soft, ribbed, gray, latexfree
5722519	Prophy Cups, RA, firm, 4 web & ribbed, white, latexfree
5722520	Prophy Cups, Snap On, firm, 4 web & ribbed, white, latexfree
5722521	Prophy Cups, Snap On, soft, 4 web & ribbed, pink, latexfree

REF	Description
5722522	Prophy Cups, Screw Type, soft, 4 web & ribbed, pink, latexfree
5722525	Prophy Cups, Screw Type, soft, ribbed, gray, latexfree
5722528	Prophy Cups, Screw Type, firm, 6 web, white, latexfree
5722529	Prophy Cups, Snap On, firm, 6 web, white, latexfree
5722530	Junior Cup, RA, Natural bristle brush, white
5722531	Junior Cup, RA, Nylon bristle brush, white
5722767	ACCLEAN Prophy cups, screw type, webbed, white
5722768	ACCLEAN Prophy cups, webbed, Metal shank, white, RA
5722874	ACCLEAN Prophy cups, snap on, webbed, white

**End of List**