

IFU SPECIFICATION

Specification # L8121-ZD
IFU Rev C
Document Rev 1
CO # 20-0240

IFU, Chairside Attachment Processing Material (Normal Set and Fast Set)

Primary Supplier: Per current revision of Purchasing Master Table, as appropriate by product.

Specification Requirements:

1. Color: Black text on a white background.
2. English (en) description, translated in 31 languages: Arabic (ar), Bulgarian (bg), Chinese (zh), Croatian (hr), Czech (cs), Danish (da), Dutch (nl), Estonian (et), Finnish (fi), French (fr), German (de), Greek (el), Hebrew (he), Hungarian (hu), Icelandic (is), Italian (it), Japanese (jp), Korean (ko), Latvian (lv), Lithuanian (lt), Norwegian (no), Polish (pl), Portuguese (pt), Romanian (ro), Russian (ru), Serbian(sr), Slovak (sk), Slovenian (sl), Spanish (es), Swedish (sv), Turkish (tr)
3. Flat size: 36.00" x 19.125" +0.095" / -0.0312"
4. Folded size: 3.00" x 2.125" +0.095" / -0.0312"
5. Final folds are glued together.
6. Pharma Fold on 27# white opaque offset.

Electronic IFU

1. 32 versions of the IFU shall be controlled on the electronic IFU website per QAP-078.

Inspection:

1. Verify that the supplier is an approved supplier for this part number as stated above.
2. Inspect per IS-020.
3. Verify that the Zest Dental Solutions part number, Zest Dental Solutions lot number, and container quantity are affixed to each package, carton, container or bag.
4. Verify that the Zest Dental Solutions part number and Zest Dental Solutions lot number are detailed on the documentation included with the shipment.

Disposition:

Process in accordance with QAP-012.

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