

Ref No	Rev No.	Issue Date

packaging validation protocol

1. scope of the protocol

- manufacturer name
- product name &description

2. international references (ISO/ ASTM)

3. packaging system description

- packaging specification & dimension
- sterile barrier system description
- packaging process description
- welding parameters (machine description, welding temp & time)

4. test ambient condition

- temp & relative humidity

5. packaging system validation

- IQ

- OQ

- PQ: test methods of

- visual inspection
- dye migration test
- seal peel test

** or equivalent tests according to product nature referring to their std

6. Enclosures

- packaging samples
- test equipment printout
- Accreditation certificate (for external lab)

Arab Republic of Egypt
Egyptian Drug Authority
Central Administration
of Medical Devices
G.A. of Medical Devices Registration



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إ.ع. التسجيل
