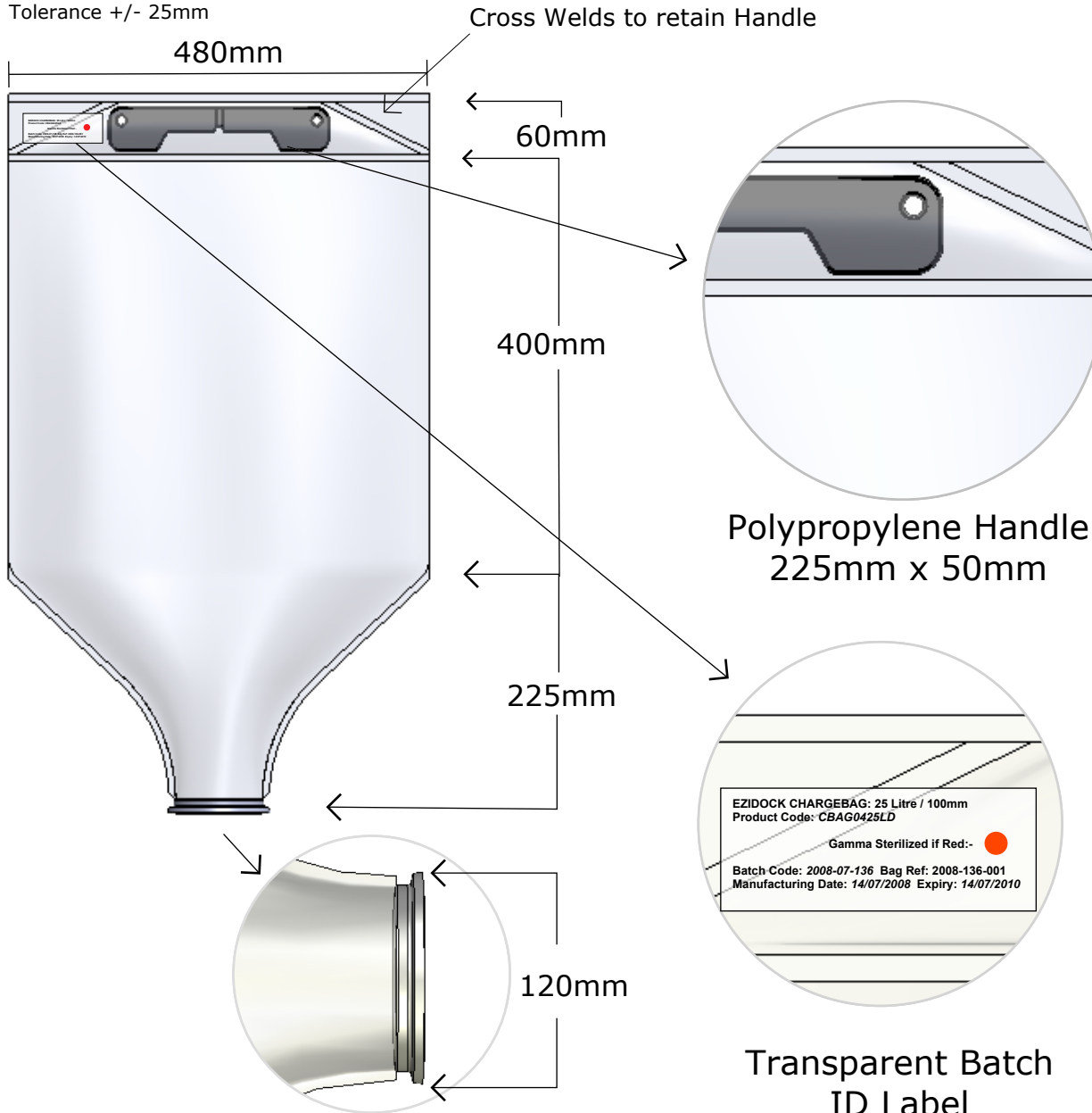


NOT DRAWN TO SCALE

Tolerance +/- 25mm



Technical Specification

Materials

This Chargebag is constructed from a 2ply, 80 micron high performance mono-extruded HD/MD/LLDPE blended film. The film is manufactured using an FDA approved Schulman Anti-Static Additive mixed at 3% which produces an average surface resistivity of $10^{11}\Omega$

The Ezidock Docking Rings are produced from an EU/FDA Food Contact approved polypropylene.

Manufacture

Ezidock Chargebags are manufactured within a Class 10,000 (UN Class 7) cleanroom environment.

All sealing equipment is approved and calibrated for the manufacture of medical devices and has PLC data capture that records individual welding temperature, time and pressure.

Final assembly and individual sleeving of Chargebags is performed under a Class 100 (UN Class 5) Laminar Airflow Cabinet.

Fully manufactured Chargebags are Gamma Irradiated to 25 kGy (min) which is indicated by a red dot indicator on both the carton and each individual Chargebag.

Testing

All Chargebags are 100% examined for visible contaminants.

Chargebags are pressure rated to 200mb - 1 in 100 is tested to destruction.

Chargebags have a maximum recommended loading of 15kgs.

Packing

25 Chargebags per carton - individually sleeved and labelled.

Relevant Certification

1. SGS System Certificate GB99/50363: ISO 13485:2003 (Manufacture under cleanroom conditions)
2. SGS System Certificate GB04/63011: ISO 9001:2000 (Design & Manufacture of Pharmaceutical components)
3. European Directive 2002/72/EEC Information Sheet (Plastics that come into contact with foodstuffs)
4. European Directive 94/62/EC Information Sheet (No metal additives; less than 100ppm)
5. AT 4073 LD; Material compliance to FDA Code 21 section 178.3130 (Antistatic Agent)
6. FA3220 Statement on Compliance to Food Contact Regulations ; FDA, CFR Title 21 (2004); 177.1520 (a) (2), (b) and (c) 2.1 Olefin Polymers.
7. British Standards Institute Certificate of Registration BRCFP 93458 PE Food Containers risk cat B.
8. British Standards Institute Certificate of Registration FS 76103 Management Systems to BS EN ISO 9001:2000.



www.ezidock.com

25 Litre Chargebag with 100mm Sanitary Fitting
Part No: CBAG0425LD Drawing No: CBAG0425

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