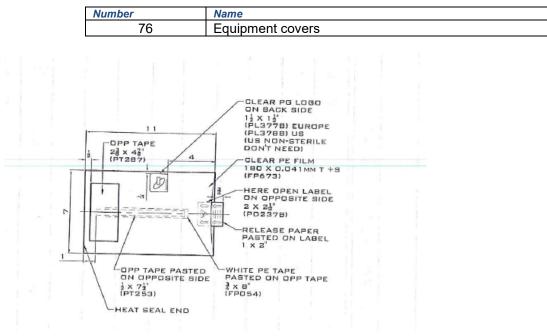


SPECIFICATION OF RAW MATERIAL

1 Family of raw materials:



2 Scope:

This specification is applicable to equipment covers - raw material of 711-1138EU

3 Description:

This raw material is composed by polyethylene

4 Specifications:

Parameter	Criteria	References
Product	PE PROBE COVER KIT SQUARE TIP, PE, 18x28cm / ADHESIVE W/GEL	Supplier Internal Method
Material	Polyethylene	Supplier Internal Method
Class		Supplier Internal Method
Rule	1	Supplier Internal Method
CFU/g	< 100 (in non sterile)	Supplier Internal Method

5 Internal Analytical criteria:

Analytical criteria are described according to Reception Bulletin Control.

6 Storage conditions:

Store in a dry place at room temperature and protect from sunlight.

- 7 References:
 - Supplier`s specification 710-1138EU TDS
- 8 Support documents for batches' approval:

Safety data sheet

Certificate of analysis according to specificationt Technical data sheet (specification and composition)/techncial design Reception Bulletin Control