

## Technical Description Connecting Tube for Drainage Bag

| Frade Name                  | Connecting Tube for Drainage Bag  |
|-----------------------------|---|
| Manufacturer                | PBN MEDICALS Denmark A/S  |
|                             | Knud Bro Alle 3   |
|                             | DK-3660 Stenlose, DENMARK   |
| Product Decription          | Connecting tubes for all types of drainage bags. Available with or without stopcocks.   |
| Classification              | ls  |
| GMDN Code                   | 45389   |
| Patent Number (if any)      | None  |
| EC Certificate              | DGM-375   |
| SO Certificate              | DGM-377   |
| Notified Body               | DGM (0543)  |
| Contains                    | Connecting tube   |
| Material                    | Hostaform <sup>®</sup> C 9021 nature and PVC  |
| Facility Certification      | PBN MEDICALS is FDA registred and certified in accordance with ISO 13485, the Medical Device<br>Directive 93/42/EEC and the canadian ISO 13485. |
| Quality Control             | Every lot of components is inspected before entering production.  |
|                             | The finish products are subject to 100% visual control.   |
| Method of Sterilization     | Ethylene Oxide  |
| Sterilization Facility      | Sterigenics Germany GmbH, Rheingaustraβe 190-196, 65203 Wiesbaden, Germany  |
| Packaging                   | Protected Unit: Individually sealed in uncoated Perfecseal® pouch and packed in a cardboard box   |
|                             | Quantity per box: Box of 25   |
|                             | Label: Conform to EN 980 and EN 1041 standards  |
| Shelf life                  | 5 years   |
| Recommandations             | Sterility guaranteed for undamaged and unopened packaging prior to use  |
|                             | Use before the expiration date on labels  |
|                             | Store in a dark, dry, cool place; Avoid extended exposure to light  |
| nformation related to Latex | Free of Latex   |