

MATERIAL SAFETY DATA SHEET

1. Product and company identification

PRODIMED

ZI, 4 avenue de l'Europe
60530 Neuilly en Thelle - FRANCE
+33(0)3 44 26 63 46
+33(0)3 44 26 93 37

Reference: 1221703 **Name Of Product:** IUI CANNULA STANDARD

2. intended use of finish product

Intrauterine artificial insemination with prepared sperm.

3. regulatory information

- Class I medical device, complying with Directive 93/42/EEC in accordance with the decree 2007/47/CE
- Single use.

4. others informations

- Latex-free.
- Individual packaging.
- Sterilised by irradiation.
- Shelf life : 5 years

5. Composition

Principal ingredient:

PEHD (all ingredients in this product are in compliance with the following chemical inventories):

United States: toxics Substances Control Act Inventory (TCSA), European Union food contact, GMP (awareness maintained at all levels, contamination prevention, effective management of change procedures, measures applied to ensure that the product is consistently suitable for the intended use).

PEBD in compliance with EU pharmacopeia (polyolefin's 3.1.3, 3.1.4) and in compliance with USP 28 « polyethylene containers ».

6. Handling and storage

Store in cool and dry place.