


Euro-pharmat information

Medical Device STERIFILT BASIC®

Updated on: 09/02/ 2020

1. Administrative information about the company	
1.1	Name: APOTHICOM DISTRIBUTION S.A.S.
1.2	Address: 52 Avenue Edison 75013 Paris France Tel : +33 (0)1 53 61 18 41 Fax : +33 (0)153 61 04 49 E-mail : infos@apothicom.org Site internet : www.apothicom.org
1.3	Contact details of the person in charge of materiovigilance: Méliné NEGRONI Tel : +33 (0)1 53 61 18 41 Fax : +33 (0)1 53 61 04 49 Email : meline.negrone@apothicom.org

2. Information about the device/equipment	
2.1	Generic name: Particle filter for syringe
2.2	Trade name: Sterifilt BASIC
2.3	GMDN nomenclature code: 46817
2.4	LPPR code * (if applicable): N/A
2.5	Medical Device Class: Is EU applicable directive: Directive 93/42/CEE Following appendix n°: V Point 3 Notified body accreditation number: 2460 First introduction into EU market: January 2007 MD manufacturer: CHIRANA T. Injecta, a.s. Nám. Dr. Alberta Schweitzera 194 916 01 Stará Turá Slovakia

2.6	<p><u>Device description:</u></p> <p>Characteristics: The Sterifilt BASIC is a syringe particle filter equipped with a polypropylene filtering membrane with 10µm pores. Sterifilt BASIC is a tool preventing the contamination risk associated with drugs injection. It is sterile and single-use. The filter is compatible with almost all syringes.</p> <div style="display: flex; justify-content: space-around; align-items: center;">  <ul style="list-style-type: none"> - Membrane diameter: 10 mm, - Filtration area: 0,77 cm². </div>
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2.7	<p><u>Description of catalogue references and packaging:</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Trade name</th> <th style="text-align: center;">Reference</th> <th style="text-align: center;">Designation/Specificity</th> <th style="text-align: center;">Packaging</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Sterifilt Basic</td> <td style="text-align: center;">AP02-001-00</td> <td>Syringe particle filter with (10-µm) membrane.</td> <td>Rigid individual sterile blister package Box of 100 units Carton of 4,000 units</td> </tr> <tr> <td style="text-align: center;">Sterifilt Basic</td> <td style="text-align: center;">AP02-001-00/B100</td> <td>Syringe particle filter with (10-µm) membrane.</td> <td>Medium individual sterile blister package Box of 100 units Carton of 4,000 units</td> </tr> </tbody> </table>	Trade name	Reference	Designation/Specificity	Packaging	Sterifilt Basic	AP02-001-00	Syringe particle filter with (10-µm) membrane.	Rigid individual sterile blister package Box of 100 units Carton of 4,000 units	Sterifilt Basic	AP02-001-00/B100	Syringe particle filter with (10-µm) membrane.	Medium individual sterile blister package Box of 100 units Carton of 4,000 units
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2.8	<p><u>Device's composition:</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Parts:</th> <th style="text-align: left;">Material:</th> </tr> </thead> <tbody> <tr> <td>Filter's body</td> <td>Polypropylene (PP)</td> </tr> <tr> <td>Membrane</td> <td>Polypropylene (PP)</td> </tr> </tbody> </table> <p><u>Additional information regarding these components:</u> Sterifilt BASIC: Latex free Phthalates (DHP) free PVC free Substance of animal or biological origin free</p> <p>Packaging: PVC free for the flexible blister package (reference AP02-005-00 / S-SO)</p> <p><u>Associated device and accessories to list:</u> N/A</p>	Parts:	Material:	Filter's body	Polypropylene (PP)	Membrane	Polypropylene (PP)
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Filter's body	Polypropylene (PP)						
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2.9	<p><u>Purpose of use:</u></p> <p>The Sterifilt BASIC is a syringe particle filter designed for people who inject drugs (PWID). It was exclusively developed in the field of harm reduction related to drugs injection. It aims at reducing the risks associated with the injection of street drugs and medicine diverted from their intended use. It removes most insoluble particles from the solution to be injected. It is more efficient than the cotton filters, usually used by PWID.</p>
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3. Sterilisation process:

Sterile MD: YES
Device sterilisation mode: Ethylene Oxide

4. Storage and preservation conditions	
Expiration period: 5 years	Normal conditions of preservation and storage.

5. Safety of use	
5.1	Technical safety: N/A
5.2	Biological safety : N/A

6. Instructions for use	
6.1	Instructions for use: IFU (instructions for use), appendix 1
6.2	Indications : Idem 2-9
6.3	Precautions for: IFU (instructions for use), appendix 1
6.4	Contraindications: N/A

7. Additional information on the device	
	<u>Bibliography, clinical trials reports, pharmaco-economic studies, improvement of the provided service, specific recommendations for use (treatment restrictions, technical platform, operator qualification etc.):</u> N/A

8. Appendices list (if any)	
	Appendix: IFU