

Product Information

1. Technical Information

1.1	Article number:	4063000, 4063001
1.2	Product name:	Intrafix® SafeSet
1.3	Product description:	IV administration sets with air vent for pressure and gravity infusions
1.4	List of materials:	see attachments
1.5	Form of delivery:	☒ sterile ☐ non-sterile ☐ non-sterile/bulk
1.6	Latex free (free of natural rubber):	☒ yes ☐ no
1.7	Does the product contain any materials according to paragraph 57 of the REACH regulation? if yes, which	☐ yes ☒ no
1.8	Shelf life:	5 years ☐ 3 years ☐ 2 years ☒ not applicable ☐
1.9	Bioburden:	our non-sterile products do not exceed the Bioburden value of 200 KBE
1.10	Instructions for use:	☒ yes, see attachments ☐ not applicable

2. Information about sterilization

2.1	for non-sterile products: is a sterilization with ethylene oxide possible?	☐ yes ☐ no
2.2	for sterile products: sterilization method:	☐ ethylene oxide ☒ radiation
	is a re-sterilization with ethylene oxide possible? (no reprocessing!)	☐ yes ☐ no ☒ no experienced data

3. Information of CE marking

3.1	Is the product CE marked?	☒ yes ☐ no identification number of the Notified Body 0123
3.2	Classification according Council Directive 93/42/EEC Annex IX: class: IIa	rule: 2

Attachments: ISO 13485 Certificate, Declaration of conformity for CE marked products, EC Certificate, list of materials, if applicable instruction for use

All data refer to typical single values and may be subject to alterations, valid without signature.
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